SIMULATIONS PLUS INC
Form 10-K
November 28, 2014
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended August 31, 2014

or

[ ] 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: 001-32046

Simulations Plus, Inc.
(Exact name of registrant as specified in its charter)

California	**95-4595609**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
42505 Tenth Street West	
Lancaster, CA 93534-7059	**(661) 723-7723**
(Address of principal executive offices including zip code)	(Registrant’s telephone number, including area code)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	**NASDAQ Stock Market LLC**

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT: 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 [X]

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 [X]

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 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 filings requirements for the past 90 days Yes [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) 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 the 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)

[X] 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 [X]

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of February 28, 2014, based upon the closing price of the common stock as reported by The Nasdaq Stock Market on such date, was approximately $57,581,229. This calculation does not reflect a determination that persons are affiliates for any other purposes.

As of November 26, 2014, 16,841,114 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement to be delivered to its shareholders in connection with the registrant's 2015 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Such definitive proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this annual report.

Simulations Plus, Inc.
FORM 10-K
For the Fiscal Year Ended August 31, 2014

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Forward-Looking Statements

This document and the documents incorporated in this document by reference contain forward-looking statements that are subject to risks and uncertainties. All statements other than statements of historical fact contained in this document and the materials accompanying this document are forward-looking statements.

The forward-looking statements are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Frequently, but not always, forward-looking statements are identified by the use of the future tense and by words such as “believes,” expects,” “anticipates,” “intends,” “will,” “may,” “co “would,” “projects,” “continues,” “estimates” or similar expressions. Forward-looking statements are not guarantees of future performance and actual results could differ materially from those indicated by the forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward-looking statements.

The forward-looking statements contained or incorporated by reference in this document are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (“Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (“Exchange Act”), and are subject to the safe harbor created by the Private Securities Litigation Reform Act of 1995. These statements include declarations regarding our plans, intentions, beliefs or current expectations.

Among the important factors that could cause actual results to differ materially from those indicated by forward-looking statements are the risks and uncertainties described under “Risk Factors” in our other filings with the Securities and Exchange Commission (“SEC”).

Forward-looking statements are expressly qualified in their entirety by this cautionary statement. The forward-looking statements included in this document are made as of the date of this document and we do not undertake any obligation to update forward-looking statements to reflect new information, subsequent events or otherwise, except as required by law.

PART I

ITEM 1 – BUSINESS

As used in this report, each of the terms “we,” “us,” “our,” the “Company” and “Simulations Plus” refers to Simulations Plus, Inc. and Cognigen Corporation, unless otherwise stated or the context otherwise requires.

OVERVIEW

Simulations Plus, Inc., incorporated in 1996, is a premier developer of groundbreaking drug discovery and development software for mechanistic modeling and simulation. Our software is licensed to major pharmaceutical, biotechnology, agrochemical, and food industry companies and to regulatory agencies worldwide for use in the conduct of industry-based research. We also provide consulting services to these industries. Recently, we have been exploring the application of some of our machine-learning technologies for problems in aerospace and healthcare outside of our traditional markets. Simulations Plus is headquartered in Southern California and its common stock trades on the NASDAQ Capital Market under the symbol “SLP.”

After the end of our 2014 fiscal year, in September 2014, Simulations Plus acquired Cognigen Corporation (Cognigen) as a wholly owned subsidiary. The acquisition is expected to add approximately $5 million to our revenues for the fiscal year ended August 31, 2015.

Cognigen, incorporated in 1992, is a leading provider of population modeling and simulation contract research services for the pharmaceutical and biotechnology industries. Cognigen’s clinical pharmacology-based consulting services include pharmacokinetic and pharmacodynamic modeling, clinical trial simulations, data programming, and technical writing services in support of regulatory submissions. Cognigen develops software for harnessing cloud-based computing in support of modeling and simulation activities and provides consulting services to improve interdisciplinary collaborations and R&D productivity.

We are a global leader focused on improving the ways scientists use knowledge and data to predict the properties and outcomes of pharmaceutical and biotechnology agents, and one of only two global companies who provide a wide range of preclinical and clinical consulting services and software. Our innovations in integrating new and existing science in medicinal chemistry, computational chemistry, pharmaceutical science, biology, and physiology into our software have made us the leading software provider for physiologically based pharmacokinetics (PBPK) modeling and simulation.

We generate revenue by delivering relevant, cost-effective software and creative and insightful consulting services. Pharmaceutical and biotechnology companies use our software programs and scientific knowledge to guide discovery and preclinical development programs. They also use it to enhance their understanding of the properties of potential new medicines and to use emerging data to improve formulations, select and justify dosing regimens, support the generics industry, optimize clinical trial design, and simulate outcomes in special populations, such as the elderly and pediatric patients.

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PRODUCTS

General

Simulations Plus develops and produces software for use in pharmaceutical research and in the education of pharmacy and medical students, as well as provides contract consulting services to the pharmaceutical and chemical industries. Our wholly owned subsidiary, Cognigen, conducts high-quality analysis and regulatory report generation for data gathered during clinical trials of new and existing pharmaceutical products. Cognigen also has developed a proprietary software product called KIWI™ which is used internally and by some of its customers to access data and analysis results on Cognigen's internal computer cloud. Each business division is discussed separately below, followed by a discussion of the expected synergies from the combination of Simulations Plus and Cognigen.

Simulations Plus

We currently offer six software products for pharmaceutical research: three simulation programs that provide time-dependent results based on solving large sets of differential equations: GastroPlus™, DDDPlus™, and MembranePlus™; and three programs that are based on predicting and analyzing static (not time-dependent) properties of chemicals: ADMET Predictor™, MedChem Designer™, and MedChem Studio™. We call the combination of ADMET Predictor, MedChem Designer and MedChem Studio our ADMET Design Suite™. After years in development, MembranePlus was released in October 2014 after the close of the current reporting period.

GastroPlus

Our flagship product and largest source of revenues is GastroPlus. GastroPlus simulates the absorption, pharmacokinetics, and pharmacodynamics of drugs administered to humans and animals, and is currently the most widely used software of its type in pharmaceutical companies, the U.S. Food and Drug Administration (FDA), the U.S. National Institutes of Health (NIH), and other government agencies in the U.S. and other countries. Because of the widespread use of GastroPlus, we were the only non-European company invited to join the European Innovative Medicines Initiative (IMI) program for Oral Bioavailability Tools (OrBiTo). OrBiTo is an international collaboration among 27 industry, academic, and government organizations working in the area of oral absorption of pharmaceutical products. Because we are outside of Europe, our participation in this project is at our own expense, while other members are compensated for their work; however, we are a full member with access to all of the data and discussions of all other members. We believe participation in this initiative enables us to benefit from and to contribute to advancing the prediction of human oral absorption from preclinical data, and ensures that we are in front of the audience of member pharmaceutical companies and regulatory agencies.

After the end of our 2014 fiscal year, in September 2014, we entered into a research collaboration agreement (RCA) with the FDA to enhance the Ocular Compartmental Absorption and Transit (OCAT™) model within the Additional Dosing Routes Module of GastroPlus to provide a tool for generic companies and the FDA to assess the likely bioequivalence of generic drug formulations dosed to the eye. Under this RCA, we receive $200,000 per year. This RCA may be renewed for up to a total of three years based on the progress achieved during the project.

Because we did not want our customers to have to wait for the next major release, an interim release of GastroPlus, version 8.6, was released in August 2014, adding two important requested capabilities: (1) the addition of minipig physiology – a species becoming common in preclinical research; and (2) the expansion of the Drug-Drug Interaction (DDI) Module to include population simulations.

The next major release, version 9.0, is already in development. This version will add the ability to simulate dermal (through the skin) drug absorption from creams and ointments. This capability was developed through a funded collaboration with a top-5 pharmaceutical company, and is currently in use at the customer's sites. A number of other improvements will be included in version 9.0 that will be announced with the release of the product, and which we believe will expand the market for GastroPlus in pharmaceutical research and development. We currently expect release of version 9.0 in December 2014 or early in 2015.

DDDPlus

DDDPlus simulates *in vitro* laboratory experiments used to measure the rate of dissolution of the drug and, if desired, the additives (excipients) in a particular dosage form (e.g., tablet or capsule) under a variety of experimental conditions. This software program is used by formulation scientists in industry and the FDA to (1) understand the physical mechanisms affecting the dissolution rate for various formulations, (2) reduce the number of cut-and-try attempts to design new drug formulations, and (3) design *in vitro* dissolution experiments to better mimic *in vivo* conditions.

MembranePlus™

MembranePlus is a new product that has been under development for a number of years, but was put on hold for several years due to other priorities. The development effort was revived in the past year and the program was released in October 2014 after the close of the current reporting period. Similar to DDDPlus, MembranePlus simulates laboratory experiments, but in this case, the experiments are for measuring permeability of drug-like molecules through various membranes, including several different cell cultures (Caco-2, MDCK) as well as artificially formulated membranes (PAMPA). The value of such a simulation derives from the fact that when the permeabilities of the same molecules are measured in different laboratories, results are often significantly different. These differences are caused by a complex interplay of factors in how the experiment was set up and run. MembranePlus simulates these experiments with their specific experimental details, and this enables the scientist to better interpret how results from specific experimental protocols can be used to predict permeability in human and animals, which is the ultimate goal. We believe MembranePlus is unique and customers have expressed interest in the new capability.

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ADMET Predictor™

ADMET (Absorption, Distribution, Metabolism, Excretion, and Toxicity) Predictor is a chemistry-based computer program that takes molecular structures as inputs and predicts approximately 145 different properties for them at an average rate of over 100,000 compounds per hour. This capability allows chemists to generate estimates for a large number of important molecular properties without the need to synthesize and test the molecules, or to generate estimates of unknown properties for molecules that have been synthesized but for which only a limited number of experimental properties have been measured. Thus, a chemist can assess the likely success of a large number of existing molecules in a company's chemical library, as well as molecules that have never been made, by providing their molecular structures, either by drawing them using a tool such as our MedChem Designer software, or by automatically generating large numbers of molecules using various computer algorithms, including those embedded in our MedChem Studio software.

ADMET Predictor has been top-ranked for predictive accuracy in peer-reviewed, independent comparison studies, while generating its results at a high throughput rate. Although the state-of-the-art of this type of software does not enable identifying the best molecule in a series, it does allow early screening of molecules that are highly likely to fail as potential drug candidates (i.e., the worst molecules, which is usually the majority of a chemical library) before synthesizing and testing them. Thus, millions of compounds can be created and screened in a day, compared to potentially months or years of work to actually synthesize and test a much smaller number of actual compounds.

During fiscal year 2014, we released version 7.1 of ADMET Predictor. This new version incorporates a powerful new model for predicting ionization constants (pKa's), developed in a collaboration with Bayer AG that enabled us to more than double the size of our data set from about 16,000 pKa values to more than 35,000, and to expand the chemical space it covers to include a larger number of molecules more like those of interest to the pharmaceutical industry today. We believe the resulting improvement in pKa prediction will further differentiate our best-in-class model from any competitor**.** Predicting ionization is critical to predicting most other properties, so all of our models (approximately 144) were retrained based on this new capability for version 7.1.

The ADMET Modeler™ subprogram that is integrated into ADMET Predictor enables scientists to use their own experimental data to quickly create proprietary high-quality predictive models using the same powerful modeling methods we use to build our top-ranked property predictions. Pharmaceutical companies expend substantial time and money conducting a wide variety of experiments on new molecules each year, resulting in large databases of experimental data. Using this proprietary data to build predictive models can provide a second return on their investment; however, model building has traditionally been a difficult and tedious activity performed by specialists. The automation in ADMET Modeler makes it easy for a scientist to create very powerful models with a minimum of training.

We are currently examining two different applications of this modeling engine: (1) building predictive models for missile aerodynamic force and moment coefficients as a function of missile geometry, Mach number, and angle of attack, and (2) classifying patients as healthy or experiencing some disease state or genetic disorder evidenced by

magnetic resonance imaging (MRI) of the brain. Other potential applications for this modeling engine have also been identified; however, our focus to date has been in these two areas.

The aerodynamic coefficient prediction problem was identified by the aerospace engineering department at Auburn University. Working with them, we have done some preliminary testing of the ADMET Modeler modeling engine for this type of problem. Results have been encouraging, and we believe there are government agencies and industrial aerospace companies that will find such a capability to be useful. To this end, we are developing a prototype AEROModeler™ program to test this concept and to use as a demonstrator for proposal efforts directed to potential funding agencies. A joint Simulations Plus/Auburn University scientific poster was accepted for presentation at the National Space and Missile Material Symposium/Commercial and Government Responsive Access to Space Technology Exchange (NSMMS/CRASTE) Conference in Huntsville, Alabama, in June 2014, and received attention and positive feedback from both government agencies and aerospace contractors, not only for aerodynamic coefficient predictions, but also for application to several other potential problems of interest to the industry.

The analysis of magnetic resonance imaging (MRI) data to classify patients as healthy or (in our first proof-of-concept case) likely to experience a form of autism has been developed in cooperation with the MRI facility at Auburn University. This state-of-the-art facility has two MRIs –a 3-Tesla machine and a 7-Tesla machine. The amount of data from MRI imaging is massive, requiring us to modify our code to handle much larger data arrays than our previous applications have required. Our current goal is to demonstrate the potential of our modeling technology to provide useful classification of a patient into one of the four groups based only on MRI data, so that we can approach various agencies (such as the NIH) to obtain funding to develop a commercial product. We presented a scientific poster at the Fourth Biennial Conference on Resting State/Brain Connectivity hosted by the Massachusetts Institute of Technology in September 2014 that received interest from a number of researchers working in this area. We believe our artificial neural network ensemble modeling engine has various applications and we intend to pursue funding to develop customized tools based on the engine for a number of potential applications.

MedChem Designer™

MedChem Designer was launched in 2011. It was initially a molecule drawing program, or "sketcher", but now has capabilities exceeding those of other molecule drawing programs because of its integration with both MedChem Studio and ADMET Predictor. We provide MedChem Designer for free to our customers because we believe that in the long run it will help to increase demand for ADMET Predictor and MedChem Studio, and because most other existing molecule drawing programs are also provided for free. Our free version includes a small set of ADMET Predictor best-in-class property predictions, allowing the chemist to modify molecular structures and then see a few key properties very quickly. With a paid ADMET Predictor license the chemist would see the entire 145 predictions that are available.

When used with a license for ADMET Predictor, MedChem Designer becomes a *de novo* molecule design tool. With it, a researcher can draw one or more molecular structures, then click on the ADMET Predictor icon and have over 140 properties for each structure calculated in seconds, including our proprietary ADMET Risk™ index. Researchers can also click on an icon to generate the likely metabolites of a molecule and then predict all of the properties of those metabolites from ADMET Predictor, including their ADMET Risk scores. This is important because a metabolite of a molecule can be therapeutically beneficial (or harmful) even though the parent molecule is not.

Our proprietary ADMET Risk score provides a single number that tells the chemist how many default threshold values for various predicted properties were crossed (or violated) by each structure. The rules can be modified and new rules added by the user to include any desired rule set based on any combination of calculated descriptors, predicted properties, and user inputs. Thus, in a single number, the chemist can instantly compare the effects of different structural changes in many dimensions. The ideal score is zero; however, a low score greater than zero might be acceptable, depending on what property(s) caused the points to be assigned. If the number is too high (greater than 5-6), the molecule is not likely to be successful as a drug. As chemists attempt to modify structures to improve one property, they often cause others to become unacceptable. Without ADMET Risk, the chemist would have to individually examine many key properties for each new molecule (and its metabolites) to determine whether any of them became unacceptable as a result of changing the structure.

During fiscal year 2014, we released version 3.0 of MedChem Designer, which added the ability to capture the image of a molecular structure from a variety of publication files with a new snapshot tool, and then have the program automatically convert the graphic image into any of several computer-based chemical structure files. Converting from lines and letters on the screen to an exact chemical representation of the molecule (Optical Structure Recognition, or OSR) is a complex task. Although a few OSR programs are in existence, we are not aware of any that can accurately convert as many varieties of images to chemical representation as the OSR tool within MedChem Designer. Such a capability allows chemists to quickly capture molecular structures from the scientific literature to use for various purposes, including for use in our simulation and modeling software programs.

MedChem Studio™

MedChem Studio is a tool that is used both for data mining and for *de novo* design of new molecules. In its data-mining role, MedChem Studio facilitates searching of large chemical libraries to find molecules that contain identified substructures, and it enables rapid generation of clusters (classes) of molecules that share common substructures from high throughput screening (HTS) data. MedChem Studio version 4.0 was released during fiscal year 2014.

While MedChem Designer can be used to refine a small number of molecules, MedChem Studio can be used to create and screen (with ADMET Predictor) a very large number of molecules down to a few promising lead candidates. MedChem Studio has features that enable it to generate new molecular structures using a variety of *de novo* design methods. When MedChem Studio is used with ADMET Predictor and MedChem Designer (which we refer to as our ADMET Design Suite), we believe the programs provide an unmatched capability for chemists to search through large libraries of compounds that have undergone high-throughput screening experiments to find the most promising classes (groups of molecules with a large part of their structures the same) and molecules that are active against a particular target. In addition, MedChem Studio can take an interesting (but not acceptable) molecule and, using a variety of design algorithms, quickly generate many thousands to millions of high quality analogs (similar new molecules). These molecules can then be screened using ADMET Predictor to find molecules that are both active against the target as well as acceptable in a variety of ADMET properties.

NCE Projects

During late 2012, we initiated a new molecule (NCE, or New Chemical Entity) design project in which we used our own products to design novel molecules and have them synthesized and tested. Our goal was to demonstrate the ability of our ADMET Design Suite to generate new lead molecules in a fraction of the time and cost normally required in the pharmaceutical industry. We have conducted two NCE design projects. In the first, we designed molecules to test against the malaria parasite and in the other we designed molecules to test against the cyclo-oxygenase-2 (COX-2) enzyme that is the target for Celebrex®. Both projects were successful in that when the molecules that we designed were tested against the malaria parasite and the COX-2 enzyme, the molecules successfully inhibited the malaria parasite and the COX-2 enzyme. We believe these projects demonstrate that our ADMET Design Suite can save considerable time and money in developing new lead compounds for particular targets. We have generated revenue from new software sales that resulted from presenting our results of the malaria parasite project.

Contract Research and Consulting Services

Our employees have expertise in oral absorption and pharmacokinetics. They have been speakers or presenters at over 150 scientific meetings worldwide in the past four years. We frequently conduct contracted studies for large customers (including the largest five pharmaceutical companies) who have particularly difficult problems and who recognize our expertise in solving them, as well as for smaller customers who prefer to have studies run by our scientists rather than to license our software and train someone to use it. The demand for our consulting services has been steadily increasing, and we have expanded our Simulations Studies team to meet the increased workload. Our acquisition of Cognigen is expected to result in increased demand for the consulting services of both companies.

We currently are working with the FDA on three different RCAs: the one for the ocular model in GastroPlus described above under "--GastroPlus," and two more described below.

During fiscal year 2014, we continued to perform under our RCA with the FDA's Center for Food Safety and Applied Nutrition (CFSAN). This RCA has a five-year term that commenced in [Month Year]. FDA scientists and our scientists are using ADMET Predictor/Modeler to build predictive models for likely toxicities of food additives and contaminants. Both FDA scientists and our scientists are building a series of models to classify new compounds as toxic or nontoxic from FDA datasets. Included early on in this effort was a special modification to ADMET Predictor requested by FDA scientists to allow the user to set a minimum value for specificity or sensitivity when building a model, and this is now a standard part of the program available to all users. Sensitivity refers to how well a model identifies toxic (or any other property) compounds. A model that determined all compounds are toxic would have 100% sensitivity, because all toxic compounds would be labeled as such; however, all nontoxic compounds would also be labeled toxic. Specificity refers to how well a model distinguishes between toxic and nontoxic compounds. Increasing one usually results in decreasing the other. Depending on the purpose of the model, some scientists will prefer to train models that emphasize one statistic over the other.

During fiscal year 2014 we entered into an RCA with the FDA's Office of Generic Drugs (OGD). The objective of this RCA, which also has a five-year term, is directed toward the FDA's evaluation of mechanistic IVIVCs (*in vitro-in vivo* correlations), an approach to determine whether mechanistic absorption modeling (MAM) correlates laboratory (*in vitro*) dissolution experiments with the *in vivo* behavior of dosage forms better than traditional empirical methods.

Cognigen

We acquired Cognigen after the end of our 2014 fiscal year, on September 2, 2014. Cognigen has a reputation for high-quality analysis and regulatory reporting of data collected during clinical trials of new and existing pharmaceutical products, typically working on 30-40 drug projects per year. The analysis of clinical trial data that Cognigen performs is different from the type of consulting services offered by Simulations Plus, the former relies more on statistical models, whereas the latter relies more on mechanistic models. Statistical models rely on equations

that are shown to fit the data, but without a detailed mechanistic understanding of why they do so. Mechanistic models involve detailed science-based mathematical representations of phenomena involved in drug absorption, distribution throughout the body, metabolism, and other effects.

At recent meetings held by the FDA and other regulatory agencies, such agencies emphasized an interest in bringing physiologically based pharmacokinetics (PBPK – a core strength of Simulations Plus) into clinical pharmacology (a core strength of Cognigen). We believe the combined strengths of Cognigen and Simulation Plus will uniquely position us at the forefront of model-based drug development going forward.

PRODUCT DEVELOPMENT

Development of our software is focused on expanding product lines, designing enhancements to our core technology and integrating existing and new products into our principal software architecture and platform technology. We intend to continue to offer regular updates to our products and to continue to look for opportunities to expand our existing suite of products and services.

To date, we have developed products internally, sometimes also licensing or acquiring products, or portions of products, from third parties. These arrangements sometimes require that we pay royalties to third parties. We intend to continue to license or otherwise acquire technology or products from third parties when it makes business sense to do so. We currently have one license agreement, with Accelrys, Inc., pursuant to which a small royalty is paid to Accelrys from revenues on each license for the Metabolite module in ADMET Predictor. This license agreement continues in perpetuity and either party has the right to terminate it.

In 1997 we entered into an exclusive software licensing agreement with TSRL, Inc. (fka Therapeutic Systems Research Laboratories), pursuant to which TSRL licensed certain software technology and databases to us, and we paid royalties to TSRL. On May 15, 2014, we and TSRL entered into a termination and non-assertion agreement pursuant to which the parties agreed to terminate the 1997 exclusive software licensing agreement, As a result, the company obtained a perpetual right to use certain source code and data, and TSRL relinquished any rights and claims to any GastroPlus products and to any claims to royalties or other payments under that agreement, and we agreed to pay TSRL total consideration of $6,000,000 as follows: (a) $3,500,000 by May 20, 2014, which amount was comprised of $2,500,000 in cash and $1,000,000 worth of our common stock (which was 164,745 shares based upon the April 25, 2014 closing price per share of $6.07 per share), (b) $750,000 payable on or before April 25, 2015, (c) $750,000 payable on or before April 25, 2016, and (d) $1,000,000 payable on or before April 25, 2017. Our payment obligations described above are non-interest bearing and will be amortized at a constant rate of $150,000 per quarter until it is completely amortized, after which no further expense will be incurred. For most quarters, we expect that this will result in a savings over the royalty payments that would have been paid to TSRL if paid consistent with past practices.

MARKETING AND DISTRIBUTION

We distribute our products and offer our services in North America, South America, Europe, Japan, Australia, New Zealand, India, Singapore, and the People’s Republic of China.

We market our pharmaceutical software and consulting services through attendance and presentations at scientific meetings, exhibits at trade shows, seminars at pharmaceutical companies and government agencies, through our website, and using various communication channels to our database of prospects and customers. At various scientific meetings around the world each year there are numerous presentations and posters presented in which the research that was reported on was performed using our software. Many of these presentations were from industry and FDA scientists; some were from our staff.

Our sales and marketing efforts are handled primarily internally with our scientific team and several senior management staff assisting our marketing and sales staff with trade shows, seminars, and customer training both via the Internet and on-site. We believe that this is more effective than a completely separate sales team for several reasons: (1) customers appreciate talking directly with software developers and scientists who can answer a wide range of technical questions about methods and features in depth; (2) our scientists and engineers benefit from direct customer contact by gaining an appreciation for the environment and problems of the customer; and (3) we believe the relationships we build through scientist-to-scientist contact are stronger than relationships built through salesperson-to-scientist contacts. We also have one independent distributor in Japan and two independent representatives in China who also sell and market our products.

We provide support to the GastroPlus User Group in Japan, which was organized by Japanese researchers in 2009. As of early 2013, a group of scientists in Europe and North America have organized another group following the example set in Japan. Nearly 500 members have joined this group to date. We support this group through coordination of online meetings each month and managing the web site for exchange of information among members.

PRODUCTION

Our pharmaceutical software products are designed and developed by our development team in California, with locations in Lancaster, Petaluma, San Jose, and San Diego. In addition, we have one team member working out of North Carolina and our Chief Executive Officer works primarily from Auburn, Alabama.

The principal materials and components used in the manufacture of simulation software products include CD-ROMs and instruction manuals, which are also produced in-house and through outside contractors. In-house graphic art and engineering talent enables us to accomplish this production in a cost-efficient manner.

COMPETITION

In our pharmaceutical software and services business, we compete against a number of established companies that provide screening, testing and research services, and products that are not based on simulation software. There are also software companies whose products do not compete directly with, but are sometimes closely related to, ours. Our competitors in this field include some companies with financial, personnel, research and marketing resources that are larger than ours. Our management believes there is currently no significant competitive threat to GastroPlus, DDDPlus, or MembranePlus; however, in spite of a barrier to entry, one could be developed over time. MedChem Studio, MedChem Designer, and ADMET Predictor/ADMET Modeler operate in a more competitive environment. Several other companies presently offer simulation or modeling software, or simulation-software-based services, to the pharmaceutical industry.

Major pharmaceutical companies conduct drug discovery and development efforts through their internal development staffs and through outsourcing. Smaller companies generally need to outsource a greater percentage of this research. Thus, we compete not only with other software suppliers, but also with the in-house development teams at some of the larger pharmaceutical companies.

Although competitive products exist, both new licenses and license renewals for GastroPlus have continued to grow in spite of this competition. We believe that we enjoy a significant market share in this segment. We believe that the success of our two NCE projects in which we designed, synthesized, and tested new molecules to treat malaria as well as COX-2/COX-1 will further promote the abilities of our ADMET Design Suite for rapid and cost-effective design of lead compounds.

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We believe the key factors in our ability to successfully compete in this field are our ability to: (1) continue to invest in research and development, and develop and support industry-leading simulation and modeling software and related products and services to effectively predict activities and ADMET-related behaviors of new drug-like compounds, (2) design new molecules with acceptable activity and ADMET properties, (3) develop and maintain a proprietary database of results of physical experiments that serve as a basis for simulated studies and empirical models, (4) attract and retain a highly skilled scientific and engineering team, and (5) develop and maintain relationships with research and development departments of pharmaceutical companies, universities and government agencies.

We actively seek acquisitions to expand the pharmaceutical software and services business. In July 2014 we signed a merger agreement with Cognigen. The merger closed on September 2, 2014, subsequent to the end of fiscal year 2014. We plan to continue our efforts to find strategic targets and alliances that will enhance our position in the industry.

TRAINING AND TECHNICAL SUPPORT

Customer training and technical support are important factors in customer satisfaction for our pharmaceutical products, and we believe we are an industry leader in providing customer training and technical support in our business areas. We provide in-house seminars at customers' and potential customers' sites, as well at selected universities to train students who will soon be industry scientists. These seminars often serve as initial training in the event the potential customer decides to license or evaluate our software. Technical support is provided after the sale of any software in the form of on-site training (at the customer's expense), web meetings and telephone, fax, and e-mail assistance to the customer's users during the customer's license period.

Technical support for pharmaceutical software is provided by our life sciences team and our inside sales and support staff based at our headquarters facilities in Lancaster, California. We provide free telephone support offering toll-free numbers in the U.S. and Canada, and e-mail and web-based support for all of our pharmaceutical software products worldwide. Technical support for pharmaceutical software products is minimal, averaging a few person-hours per month.

RESEARCH AND DEVELOPMENT

Research and development (R&D) activities include both enhancement of existing products and development of new products. Development of new products and adding functionality to existing products are capitalized in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 985-20, "Costs of Software to Be Sold Leased, or Marketed". R&D expenditures, which primarily relate to both capitalized and expensed salaries, R&D supplies, laboratory testing, and R&D consulting, were approximately $2,322,000 during fiscal year 2014, of which $1,369,000 was capitalized. R&D expenditures during fiscal year 2013 were approximately

$1,931,000, of which $1,129,000 was capitalized.

Our pharmaceutical business R&D activities during fiscal year 2014 were focused on improving our ADMET Predictor/ADMET Modeler, MedChem Studio, MedChem Designer and GastroPlus products, as well as the development of our new MembranePlus software product described above.

EMPLOYEES

As of August 31, 2014, Simulations Plus employed 30 full-time employees, including 22 in research and development, 4 in marketing and sales, 4 in administration and accounting. An additional Ph.D. level employee joined Simulations Plus in September 2014. Currently 16 employees hold Ph.Ds. in their respective science or engineering disciplines. Additionally, 6 employees hold one or more Master's degrees. Most of the senior management team and the members of our Board of Directors hold graduate degrees.

The Cognigen acquisition added 35 full-time employees, bringing our total workforce to 66.

We believe that our future success will depend, in part, on our ability to continue to attract, hire and retain qualified personnel. We continue to seek additions to our life sciences team although the competition for such personnel in the pharmaceutical industry is intense. None of our employees is represented by a labor union, and we have never experienced a work stoppage. We believe that our relations with our employees are good.

INTELLECTUAL PROPERTY AND OTHER PROPRIETARY RIGHTS

We own two patents that were acquired as part of our acquisition of certain assets of Bioreason, Inc. We primarily protect our intellectual property through copyrights and trade secrecy. Our intellectual property consists primarily of source code for computer programs and data files for various applications of those programs in the pharmaceutical software businesses. The expertise of our staff is a considerable asset closely related to intellectual property, and attracting and retaining highly qualified scientists and engineers is essential to our business.

EFFECT OF GOVERNMENT REGULATIONS

Our pharmaceutical software products are tools used in research and development and are neither approved nor approvable by the FDA or other government agencies.

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ITEM 1A – RISK FACTORS

Not applicable because we are a smaller reporting company.

ITEM 1B – UNRESOLVED STAFF COMMENTS

None.

ITEM 2 – PROPERTIES

We lease approximately 13,500 square feet of space in Lancaster, California. The original lease had a five-year term with two, three-year options to extend. Following the expiration of initial five-year term in February 2011, we exercised the first of the three-year options which extended the lease to February 2, 2014. In June 2013, the lease was amended extending the term to February 2, 2017. As amended, the lease provides for an annual base rent increase of 3% per year and two, two-year options to extend the term. The current base rent amount is $24,272 per month; however, we had three months' free base rent during the months of June, July and August of 2013. We record these three months as a discount divided equally through the initial term of the amended lease from June 2013 through January 2017.

The Company believes its existing facilities and equipment are in good operating condition and are suitable for the conduct of its business.

ITEM 3 – LEGAL PROCEEDINGS

Except as described below, we are not a party to any legal proceedings and are not aware of pending legal proceedings of any kind.

In June 2014, the Company was served with a complaint in a civil action entitled Sherri Winslow v. Incredible Adventures, Inc., et al. (Los Angeles Superior Court Case No. BC545789) alleging wrongful death and seeking unspecified damages arising out of a May 18, 2012 plane crash in the State of Nevada. The Company's Chief

Executive Officer owns the subject aircraft and is also a named defendant. The complaint alleged that the Company was the owner of the subject aircraft. The Company denies all material allegations against it, including that it owns or has ever owned any interest in the subject aircraft. On November 25, 2014, the plaintiff and the Company signed a stipulation of dismissal pursuant to which the plaintiff agreed to dismiss the Company without prejudice. If the plaintiff does not discover evidence during a nine month period to and including August 31, 2015 that justifies bringing the Company back into the litigation, the Company will prepare a dismissal with prejudice to be signed on behalf of the plaintiff.

ITEM 4 – MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5 – MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

The Company's common stock trades on the NASDAQ Capital Market under the symbol "SLP."

Price Range of Common Stock

The following table shows low and high sales price for the Company's common stock for the last eight fiscal quarters.

	Low Sales Price	High Sales Price
FY14:		
Quarter ended August 31, 2014	5.43	7.00
Quarter ended May 31, 2014	5.61	6.76
Quarter ended February 29, 2014	4.86	6.08
Quarter ended November 30, 2013	4.70	5.41
FY13:		
Quarter ended August 31, 2013	4.01	4.83
Quarter ended May 31, 2013	3.92	4.39
Quarter ended February 29, 2013	4.01	4.59
Quarter ended November 30, 2012	4.38	4.80

Holders

As of November 26, 2014, there were 47 shareholders of record.

Dividends

We paid a total of $3.1 million and $4.0 million in cash dividends during fiscal years 2014 and 2013, respectively, as set forth in the table below. We expect to pay quarterly dividends of $0.05 per share of common stock each quarter,

subject to declaration by our Board of Directors. However, there can be no assurances that our Board of Directors will continue the dividend distributions for any specified number of quarters.

Fiscal Year	Record Date	Distribution Date	# of Shares Outstanding on Record Date	Dividend per Share		Total Amount
2013	11/8/2012	11/13/2012	15,927,806	$0.05		$796,390
	12/24/2012	12/28/2012	16,021,309	$0.14	*	$2,242,983
	5/7/2013	5/10/2013	16,030,433	$0.03	**	$480,913
	8/12/2013	8/15/2013	16,030,894	$0.03	**	$480,926
	11/08/2013	11/15/2013	16,073,894	$0.04	**	$642,956
2014	2/17/2014	2/24/2014	16,149,460	$0.05		$807,473
	5/09/2014	5/16/2014	16,165,171	$0.05		$808,259
	8/04/2014	8/11/2014	16,337,955	$0.05		$816,897

* As a tax benefit to shareholders considering the increase in federal income tax for capital gains in 2013, the Board of Directors declared an accelerated cash dividend of $0.14 per share on December 14, 2012, consisting of all of the planned February 2013 dividend of $0.05 per share, plus $0.03 per share of the planned $0.05 dividend per quarter per share for the remaining three fiscal quarters ending in calendar year 2013.

** The Board of Directors decided to increase the May, August, and November 2013 dividend distributions from the planned $0.02 per share ($0.03 of the $0.05 per share quarterly dividend having been distributed in December 2012) to $0.03 per share in May and August 2013 and to $0.04 in November 2013.

Repurchases

There is currently no share repurchase program pending, and the Company made no repurchases of its securities within the fourth quarter of the fiscal year 2014.

ITEM 6 – SELECTED FINANCIAL DATA

Not applicable because we are a smaller reporting company.

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

The following discussion and analysis should be read in conjunction with the Financial Statements and related notes included in this Annual Report on Form 10-K.

Management Overview

Fiscal year 2014 highlights:

- In July 2014 we signed a merger agreement with Cognigen Corporation and completed the merger on September 2, 2014. As a result of this merger the Company now provides clinical trial consulting services to the pharmaceutical industry.
- In May 2014 we terminated an exclusive software licensing agreement we entered into with Therapeutic Systems Research Laboratories (TSRL) in 1997. As a result, the company obtained a perpetual right to use certain source code and data, and TSRL relinquished any rights and claims to any GastroPlus products and to any claims to royalties or other payments under the 1997 agreement. We agreed to pay TSRL total consideration of $6,000,000 payable in installments through April 2017. For most quarters, we expect that this will result in a savings over the royalty payments that would have been paid to TSRL if paid consistent with past practices.
- We released updated versions of all major software products.
- We advanced the development of our new MembranePlus™ software program for simulation of in vitro permeability experiment, which has now been released.
- We successfully completed the third year of our five-year renewable collaboration with the Center for Food Safety and Nutrition of the FDA to develop predictive toxicity models for food additives and contaminants.
- We completed a new drug design project targeting COX-2 and COX-1 enzymes. In this project, we synthesized four new molecules, and all four molecules inhibited both the COX-2 and COX-1 enzymes, and one of them provided the desired characteristic of higher affinity for COX-2 than COX-1. We believe this is a significant achievement for a software company, and that it demonstrates that our ADMET Design Suite can save considerable time and money in developing new lead compounds for particular targets.
- We expanded our technical staff by over 10%, adding one new Ph.D. and one new Masters level scientist to the Life Sciences department and one new Masters level engineer to our Computational Technologies team.
- We hosted five multi-day workshops in the United States, Europe, China, Japan, and Korea to educate users on the various features and applications of our software.
- We attended 48 scientific conferences, presenting 30 posters and oral podium lectures.
- We achieved 92% renewal rate for software licenses.
- We signed 79 new clients (includes new organizations and departments at existing clients).
- We finalized new orders for software licenses at several major regulatory agencies (including the U.S. EPA, China SFDA, and Japan PMDA).
- We realized significant growth in license revenue from Asian territories (Japan, China, Korea, and India).
- Our Board of Directors declared dividends totaling $0.19 per share ($0.04 dividend in the first quarter of fiscal year 2014 and $0.05 per share for the 2nd, 3rd and 4th quarters of fiscal year 2014).

Fiscal Year 2014 Financial Summary:

- Gross revenues increased 13.8% to $11,461,000 from $10,071,000 in fiscal year 2013
- Selling, general and administrative expenses increased 25.1% to $4,440,000 from $3,550,000 in fiscal year 2013
- Research and development expenses increased 17.2% to $2,322,000 from $1,931,000 in fiscal year 2013
- Income from continuing operations increased 9% to $4,439,000 from $2,886,000 in fiscal year 2013
- Net income exceeded $3,000,000 for the first time

Strategy Going Forward:

- Continue to advance our software offerings through both our in-house developments and our funded and unfunded collaborations with our industry and government customers
- Continue to seek acquisition and partnership possibilities to broaden our offerings of products and services
- Continue our marketing and sales campaign including attending and exhibiting at numerous scientific conferences and meetings, expanded use of social media, and expanded advertising
- Increase our marketing and sales efforts with respect to our consulting services in both pharmacokinetics and in small molecule design
- Continue to explore the application of our technologies to new markets in aerospace and healthcare