SIMULATIONS PLUS INC
Form 10-K
November 18, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

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

For the fiscal year ended August 31, 2013

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 T

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 T

Indicate by check mark whether the registrant (1) 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 T 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 T 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) T Smaller reporting company

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of February 28, 2013, based upon the closing price of the common stock as reported by The Nasdaq Stock Market on such date, was approximately $39,168,468. This calculation does not reflect a determination that persons are affiliates for any other purposes.

As of November 15, 2013, 16,041,894 shares of the registrant's common stock, par value $0.001 per share were outstanding, and no shares of preferred stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the definitive Proxy Statement to be delivered to shareholders in connection with the 2014 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this annual report.

The Exhibit Index (Item 15) lists several documents incorporated by reference.

Simulations Plus, Inc.
FORM 10-K
For the Fiscal Year Ended August 31, 2013

Table of Contents

2

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,” “cou “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.

PART I

ITEM 1 – BUSINESS

OVERVIEW

Simulations Plus, Inc. ("Simulations Plus" or the "Company," "us," "we," or "our"), which was incorporated in 1996, develops and produces software for use in pharmaceutical research and for education, as well as provides consulting and contract research services to the pharmaceutical industry. Words+, founded in 1981, produced computer software and specialized hardware for use by persons with disabilities. The Words+ subsidiary was sold effective November 30, 2011, and is treated as "discontinued operations" in the financial statements. This discussion will therefore focus on the ongoing operations for pharmaceutical software and services.

PRODUCTS

We currently offer five software products for pharmaceutical research: ADMET Predictor™, MedChem Designer™, MedChem Studio™, DDDPlus™, and GastroPlus™. A sixth product, MembranePlus™, is well along in development with testing and validation studies under way. We plan to release MembranePlus™ by March 2014.

ADMET Predictor™

ADMET (Absorption, Distribution, Metabolism, Excretion and Toxicity) Predictor is a computer program that takes molecular structures as inputs and predicts over 140 different properties for them at the rate of about 200,000 compounds per hour on a fast laptop computer. This capability allows chemists to get estimates for a large number of important properties without the need to synthesize and test the molecules. ADMET Predictor has been consistently top-ranked in peer-reviewed, independent comparison studies for predictive accuracy, while generating its results at a very high throughput rate. The current state-of-the-art of this type of software does not enable finding the best molecule in a series, but it does allow identifying molecules that are highly likely to fail as potential drug candidates (the worst molecules, which is often the majority of a chemical library) before synthesizing and testing them. Thus, millions of "virtual" compounds can be created and screened in a day, compared to potentially months of work to actually synthesize and test a much smaller number of actual compounds.

The ADMET Modeler™ subprogram that is integrated into ADMET Predictor enables scientists to use their own experimental data to quickly create high-quality, proprietary predictive models using the same powerful modeling methods we use to build our top-ranked class 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.

We released Version 6.5 of ADMET Predictor during this reporting period. This version extends our metabolism predictions by training on a much larger experimental data set, and for the first time, provides specific metabolism rates for individual atoms within a molecule, rather than only for the molecule as a whole. These improvements are also available via MedChem Designer and MedChem Studio for customers who license ADMET Predictor. We are now working on version 7.0, which we expect to release before the end of calendar 2013. This new version will incorporate a new model for predicting ionization constants (pKa's) developed in a collaboration with Bayer AG that enabled us to approximately double the size of our data set from about 16,000 pKa values to more than 30,000 and to expand the chemical space it covers to include more molecules representative of those of interest to the pharmaceutical industry today. We believe the resulting improvement in pKa prediction puts our already best-in-class model well in front of any competitor**.** Predicting ionization is critical to predicting most other properties, so all of our models (approximately 140) are being retrained based on this new capability for version 7.0.

Version 6.5 also adds confidence levels to most of our toxicity models so that users have an idea of the reliability of each individual prediction.

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 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 free. Our free version includes a small set of ADMET Predictor property predictions, allowing the chemist to modify molecular structures and then see a few key properties very quickly. The chemist also sees that with a paid ADMET Predictor license, a total of over 140 predictions would be available.

When coupled with a license for ADMET Predictor, MedChem Designer becomes a de novo design tool for medicinal chemists. With it, they 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. They can also click on an icon to generate likely metabolites and predict their properties and ADMET Risks as well. ADMET Risk provides a single number that tells the chemist how many default threshold values for 24 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. 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 separately examine many key properties for each new molecule to check whether any became unacceptable as a result of changing the structure.

We released MedChem Designer 2.5 during this reporting period. This new version now shows the chemist the specific predicted atom locations for metabolism by each of the enzymes predicted to act upon a molecule.

MedChem Studio™

Over the past several years, MedChem Studio updates have resulted in a very powerful tool for medicinal and computational chemists for both data mining and for designing new drug-like molecules. We released version 3.5 of MedChem Designer during this reporting period. The new features are too numerous to list, but include such important items as:

- A new licensing module from Flexera called FlexNet™
- Improvements to graphics in structure depictions and the Miner 3D module
- Faster performance on large data sets
- A 64-bit version is now available to deal with much larger data sets

MedChem Designer can be used to refine a small number of molecules: however, creating and screening a very large number of molecules down to a few promising lead candidates is the primary function of MedChem Studio (with ADMET Predictor). MedChem Studio has features that enable it to generate very large numbers of new molecular structures using a variety of de novo design methods. Coupled with ADMET Predictor and MedChem Designer, 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 with ADMET Predictor can take an interesting (but not acceptable) molecule and very quickly generate many thousands of high quality analogs (i.e., similar new molecules) using a variety of design algorithms to generate new molecules that are predicted (via ADMET Predictor) to be both active against the target as well as acceptable in a variety of ADMET properties.

MedChem Studio version 3.5 was released during the current reporting period, adding a number of new features, including:

- New molecular structure drawing algorithms for crisper structure depictions
- New licensing module from Flexera called FlexNet™
- Increased execution speed
- 64-bit version accesses much more memory for very large data sets
- Ability for user to define equations to calculate new attributes by combining others
- Enhanced Miner3D graphics with expanded assortment of chart types

NCE Project

Based on our strong belief in our ADMET Design Suite's (MedChem Studio/MedChem Designer/ADMET Predictor) exceptional capabilities, we initiated our own project to design new molecules (NCEs, or New Chemical Entities). After considering various targets, we selected the malaria parasite Plasmodium falciparum, both because there is an unmet need for a very low-cost cure, and because we believed that external funding opportunities might exist if we were successful in generating high-quality lead compounds using our software. Our goal was to demonstrate how well the ADMET Design Suite worked to generate new lead molecules in a fraction of the time and cost normally required in the pharmaceutical industry. We completed the design process in September 2012 and we announced that we had requested quotations from chemical synthesis companies for the cost and time to make a small set of molecules. Five molecules of our own design and two precursors (almost the final designed structures, but a step away in synthesis)

were synthesized and tested for inhibition of the parasite at the University of California at Riverside. We were hoping that at least one would show inhibition of the growth cycle of the parasite.

We were excited to learn that every molecule showed activity against the parasite at less than micromolar concentrations, with two showing activity at less than 100 nanomolar concentration (high potency) against the drug-sensitive strain of the parasite. They were then tested against the drug-resistant strain of the malaria parasite, and again potency was observed, with two molecules showing nanomolar activity. We believe this exercise – a software company using its own products to design novel molecules and have them synthesized and tested – is unprecedented.

Several of these molecules were sent to another outside laboratory for additional experiments to measure a few key properties to compare the values versus our ADMET Predictor predictions. Our predictions for solubility, ionization constants (pKa), and lipophilicity were all well within accepted tolerances. Metabolism by human liver microsomes was much faster than predicted, probably due to metabolism by pathways our models did not yet predict. These molecules were only expected to be good lead molecules, not to be final drug molecules. Further structural changes to these lead compounds might meet all requirements for an approved drug.

At this time, we are not pursuing this project any further using internal funding, but would do so if external funding can be secured, because our goal for this project was not to develop a cure for malaria. Rather, we wanted to demonstrate that our software tools can enable scientists to quickly and efficiently analyze high-throughput data, to generate new molecular structures, and to assess their qualities via ADMET Predictor, resulting in high-quality lead candidates in a small fraction of the time and cost usually required. We accomplished that and we have been presenting our results in scientific meetings and in webinars to a worldwide audience. New software license sales resulting from these presentations have already more than recovered our investment.

During this reporting period, we announced that we had completed the design of a number of new molecules for a different target – the cyclo-oxygenase-2 (COX-2) enzyme that is the target for Celebrex®. Celebrex is the only COX-2 inhibitor remaining on the market, after the withdrawal of other approved drugs (such as Vioxx®) due to cardiac toxicity. Our chemical synthesis contractor has been working on developing the synthetic methods to make these new molecules for a number of weeks and progress is encouraging. We hope to have samples of several of our new molecules, if not all of them, in the next few months, at which time we will contract for testing them against both COX-2 and COX-1 enzymes (COX-1 is inhibited by aspirin and other drugs). The reason for also testing against the COX-1 enzyme is that it appears from the scientific research that was conducted after the withdrawal of other COX-2 inhibitors from the market that it is important to inhibit both COX-2 and COX-1 at a certain ratio in order to provide the benefits of COX-2 inhibition without the cardiotoxicity risk that has been associated with inhibiting COX-2 alone. We designed our new molecules based on activity models for both COX-2 and COX-1 built from public data, with the goal of providing an acceptable ratio of COX-2 to COX-1 inhibition.

-

DDDPlus

DDDPlus simulates in vitro laboratory experiments used to measure the rate of dissolution of the drug and, if desired, the additives (excipients) contained in tablets and capsules under a variety of experimental conditions. This software program is used by formulation scientists in industry and the U.S. Food and Drug Administration (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) to design in vitro dissolution experiments to better mimic in vivo conditions.

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 in widespread use at pharmaceutical companies, the FDA, the U.S. National Institutes of Health (NIH), and other government agencies in the U.S. and other countries. Because 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 a 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.

Version 8.5 of GastroPlus was released during the current reporting period, adding a number of important new capabilities requested by customers as well as improvements we have identified in-house, including:

- A new model for precipitation based on classical nucleation theory

- Infant physiologies, including for babies born as much as 16 weeks premature

- A unique method for using transporter data from preclinical experiments to predict transporter effects in human and other animals

- A number of additional expression levels of enzymes and transporters in human and animal physiologies

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. It was revived in the past year and is now nearing commercial release. Like 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 is that when the same molecules are measured in different laboratories, results are often strikingly different. The differences are caused by a complex interplay of factors in how the experiment was set up. The ability to simulate these experiments with their specific setups in detail is provided by MembranePlus, and this enables the scientist to better interpret how results from various experiments can be used to predict permeability in human and animals, which is the ultimate goal. MembranePlus is unique and our customers have expressed significant interest in the new capability.

We plan to release version 1.0 of MembranePlus by March 2014.

Contract Research and Consulting Services

Our expertise in oral absorption and pharmacokinetics is evidenced by the fact that our staff members have been speakers or presenters at over 80 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. Long-term collaborations and shorter-term consulting contracts serve both to showcase our technologies and to build and strengthen customer relationships.

During the fourth quarter of fiscal year 2013 we continued to work on our 5-year collaboration agreement with the Center for Food Safety and Applied Nutrition (CFSAN) of the FDA. FDA scientists and our scientists are using ADMET Predictor/Modeler to build predictive models for likely toxicities of food additives and contaminants. During the first year of this collaboration, we analyzed FDA databases and worked with FDA scientists to ensure that the FDA data to be used for building new predictive models is as accurate as we can reasonably make it. Both FDA scientists and our scientists are building a series of models to classify new compounds as toxic or nontoxic from FDA datasets. Included in this effort was a special modification to ADMET Predictor to allow the user to set a minimum value for specificity or sensitivity when building a model. 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.

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 offer regular updates to our products and to continue to look for opportunities to expand our existing product suite.

We develop all of our products internally. We have also licensed products or have otherwise acquired products, or portions of our products, from other organizations. These arrangements sometimes require the payment of royalties by us. We intend to continue to license or otherwise acquire technology or products from third parties. We currently have two royalty agreements, one with TSRL, Inc. (“TSRL”) and another with Symyx Technologies (“Symyx”). In July 1997, we entered into a royalty agreement with TSRL pursuant to which royalties were paid to TSRL from revenues on each license for GastroPlus basic software. In March 2010, we entered into a royalty agreement with Symyx, which was merged with Accelrys, Inc., pursuant to which royalties were paid to Symyx from revenues on each license for Metabolite module. After we entered into a buyout agreement with Enslein Research, we combined Metabolism module and Metabolite module, and currently we pay royalties to Symyx from the sale of a new Metabolism module. These license agreements have no expiration date.

MARKETING AND DISTRIBUTION

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 web pages on the Internet, and using various communication media to our compiled database of prospects and customer names. 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.

We have one independent distributor in Japan and two independent representatives in China; however, our scientific team is also the majority of our sales and marketing team, assisting our Vice President of Marketing and Sales and his 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 developers who can answer a wide range of technical questions about methods and features in depth; (2) our scientists benefit from direct customer contact by gaining an appreciation for the environment and problems of the customer; and (3) the relationships we build through scientist-to-scientist contact are stronger than through salesperson-to-scientist contacts.

We provide support to the GastroPlus User Group in Japan, which was organized by Japanese researchers several years ago. As of early 2013, a group of scientists in Europe and North America have organized another group following the example set in Japan. The number of members who have joined this group is more than 330. We support this group as well through coordination of online meetings each month and managing the web site for exchange of information among members.

We use the Internet to provide product information and software updates, and as a forum for user feedback and information exchange. We have cultivated market share in North America, South America, Europe, Japan, Australia, New Zealand, Singapore, and the People’s Republic of China. Internet and e-mail technologies have had a positive influence on our ability to communicate with existing and potential customers worldwide.

PRODUCTION

Our pharmaceutical software products are designed and developed entirely by our development team in California, with locations in Lancaster, Petaluma, San Jose, and San Diego. 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 or DDDPlus, however, 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 some of this work. 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 dominant market share in this segment. We believe that the success of our recent NCE project in which we designed, had synthesized, and tested a number of new molecules to treat malaria has cultivated strong interest in our ADMET Design Suite™ (ADMET Predictor/MedChem Studio/MedChem Designer). Presentations in the U.S., Japan, and Europe since the results were released have been well received and new licenses for our cheminformatics software have already more than recouped our investment. Our new COX-2/COX-1 NCE project is intended to further promote the abilities of our ADMET Design Suite for rapid and cost-effective design of lead compounds.

We believe the key factors in competing in this field are our ability to develop industry-leading simulation and modeling software and related products and services to effectively predict activities and ADMET-related behaviors of new drug-like compounds, to design new molecules with acceptable activity and ADMET properties, to develop and maintain a proprietary database of results of physical experiments that will serve as a basis for simulated studies and empirical models, to attract and retain a highly skilled scientific and engineering team, and to develop and maintain

relationships with research and development departments of pharmaceutical companies, universities and government agencies.

We are actively seeking acquisitions to expand the pharmaceutical software and services business. Earlier attempts to acquire other companies have not been successful either in arriving at mutually agreeable terms and conditions, or because of adverse conditions discovered during our due diligence process.

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. 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, telephone, fax, and e-mail assistance to the customer's users during the customer's license period. We have used Internet meetings extensively to provide demonstrations and customer assistance, resulting in rapid response to requests worldwide and reducing our travel time and expenses.

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

We believe that our ability to grow and remain competitive in our markets is strongly dependent on investment into research and development ("R&D"). 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 $1,931,000 during fiscal year 2013, of which $1,129,000 was capitalized. R&D expenditures during fiscal year 2012 were approximately $1,907,000, of which $959,000 was capitalized.

Our pharmaceutical business R&D activities during fiscal year 2013 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, 2013, we employed 27 full-time employees and no part-time employees, including 19 in research and development, 4 in marketing and sales, 4 in administration and accounting. Currently 15 employees hold Ph.D.s and 1 is a Ph.D. candidate in their respective science or engineering disciplines. Additionally, 4 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. 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.

ITEM 1A – RISK FACTORS

Not applicable because we are a smaller reporting company.

ITEM 1B – UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2 – PROPERTIES

We lease approximately 13,500 square feet of space in Lancaster, California. The original agreement had a five-year term with two (2), three (3)-year options to extend. Since the original five-year term expired in February 2011, we have exercised the first of the two (2), three (3)-year options which will end on February 2, 2014. We made an amendment to our current lease with a single remaining extension of three (3) years at an annual increase of 4% per year. The amended lease extends to February 2, 2017 with an annual increase of 3% per year and has an option of two (2) two-year extensions. The current base rent amount of $24,272.42 per month remains the same; however, we had 3 months' free base rent during the months of June, July and August of 2013. We record these three (3) months as a discount divided equally through the first term of this amended lease from June 2013 through January 2017. The amended lease is filed with the SEC as an exhibit to our Form 10-Q filed on July 10, 2013.

After the sale of Words+ to Prentke Romich Company (PRC), we entered into a sublease agreement under which Words+ paid 20% of the monthly rent we pay to our landlord, plus 20% of facility-related operating expenses. The term of this month to month sublease commenced on January 1, 2012 and ended on February 28, 2013.

ITEM 3 – LEGAL PROCEEDINGS

We are not a party to any legal proceedings and are not aware of any pending legal proceedings of any kind.

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

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 2013.

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
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
FY12:		
Quarter ended August 31, 2012	3.76	4.46
Quarter ended May 31, 2012	3.66	4.61
Quarter ended February 29, 2012	2.91	4.25
Quarter ended November 30, 2011	2.97	3.24

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 2013 highlights:

- *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 is now nearing completion.*
- *We completed two funded collaboration agreements with top-5 pharmaceutical companies to extend the capabilities of our flagship GastroPlus software with an enhanced oral cavity absorption model and the ability to simulate dosing through the skin.*
- *We successfully completed the second 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 initiated a new drug design project targeting COX-2 and COX-1 enzymes and sent out requests for quotations for synthesis of these new molecules. After this reporting period we selected a contractor and development of the synthetic methods is now under way.*

- *We expanded our technical staff, adding 2 new Ph.D. scientists to the Life Sciences department and two additional engineers to form a new Computational Technologies (CT) team.*

- *Hosted 4 multi-day workshops in the United States and Europe to educate users on the various features & applications of our software*

- *Redesigned website with modern look and new interactive features*

- *Attended 55 scientific conferences, presenting 36 posters and oral podium lectures*

- *Achieved 94% renewal rate for software licenses over last 3 fiscal quarters*

- *Signed 60 new clients (includes new organizations and departments at existing clients)*

- *Finalized new orders for software licenses at several major regulatory agencies (including the U.S. FDA, U.S. EPA, and China SFDA)*

- *Achieved 27% increase in license revenue from Asian territories (Japan, China, Korea, Singapore, and Thailand).*

- *Assisted with the formation of the GastroPlus User Group, an interactive network of North American and European industry users that has created a forum for sharing best practices, addressing unmet needs, and promoting the adoption of modeling & simulation.*

- *In December 2012 during our first fiscal quarter of FY2013, the Board of Directors decided to pay an accelerated cash dividend consisting of all of the $0.05 per share dividend planned for February 2013, plus $0.03 of the planned dividends for May, August, and December 2013. This was done to provide shareholders with the benefit of the lower income tax rates in 2012 compared to the increased rates for 2013.*

- *Our Board of Directors declared increased (from $0.02) quarterly cash dividends of $0.03 per share in May and August. Recently, our Board of Directors declared a $0.04/share dividend for November 15, 2013 distribution, which is in fiscal year 2014.*

· *Our cash position remained strong, with cash at the end of the fiscal year of $10.2 million, and we have no debt.*

Fiscal year 2013 Financial Summary:

· *Gross revenues increased 6.6% to $10,071,000 from $9,449,000 in fiscal year 2012*

· *Selling, General and Administrative expenses increased 5.0% to $3,550,000 from $3,379,000 in fiscal year 2012*

· *Research and Development expenditures increased 1.3% to $1,931,000 from $1,907,000 in fiscal year 2012. In fiscal year 2012, approximately $140,000 was spent for outside services to synthesize and test the new molecules we designed to inhibit the growth of the malaria parasite. In fiscal year 2013, we did not have such an expense, resulting appearance of small increase in research and development expenditure*

· *Income from continuing operations increased 11.7% to $3,141,000 from $2,812,000 in fiscal year 2012*

11

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*

- *Seek partners for our malaria new chemical initiative to take it further into development*

- *Select a new target and repeat our drug design, synthesis, and test activities as we did for malaria to further demonstrate the capabilities of our ADMET Design Suite to generate high-quality lead compounds in a fraction of the time and cost normally required*

Fiscal year 2013 was another record year. We believe the continued growth of our pharmaceutical software and services business segment is the result of steadily increasing adoption of simulation and modeling software tools across the pharmaceutical industry, as well as the expertise we offer as consultants to assist companies involved in the research and development of new medicines. We have received a continuing series of study contracts with pharmaceutical companies ranging from several of the largest in the world to a number of medium-sized and smaller companies in the U.S. and Europe.

Our financial performance enabled us to maintain significant cash deposits, remain debt-free, and continue to invest in our marketing and sales activities we began in early 2009 in order to reach a wider customer base, as well as to distribute significant cash dividends to our shareholders.

We have not been successful in identifying and completing any acquisitions during this reporting period in spite of ongoing investigations. It is our intent to continue to search for acquisition opportunities that would be compatible with our current businesses and that would be immediately accretive, i.e., adding to both revenues and earnings.

In the past, we have used some of our cash to repurchase shares of our common stock because we believe that reducing the number of fully diluted shares provides greater value to our shareholders than receiving a low interest

rate on our cash deposits, and because we believe that our cash deposits after such repurchases remain sufficient to accomplish any reasonable potential acquisitions as well as to maintain sufficient cash reserves to ensure meeting operational needs for the foreseeable future. Although there are no stock repurchase programs pending, our Board of Directors may consider additional repurchases at any time at prices and under conditions set by our Board of Directors.

Results of Operations

The following sets forth selected items from our statements of operations (in thousands) and the percentages that such items bear to net sales for the fiscal years ended August 31, 2013 (“FY13”) and August 31, 2012 (“FY12”).

	Fiscal years ended			
	08/31/13		08/31/12	
Net sales	$10,071	100%	$9,449	100%
Cost of sales	1,647	16.4	1,510	16.0
Gross profit	8,424	83.6	7,939	84.0
Selling, general and administrative	3,550	35.2	3,379	35.8
Research and development	802	8.0	948	10.0
Total operating expenses	4,352	43.2		