SIMULATIONS PLUS INC
Form 10-K
November 14, 2018

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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, 2018

or

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

For the transition period from _____ to _____

Commission file number: 001-32046

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

(Address of principal executive offices including zip code)

(661) 723-7723

(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 o 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 o 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 o

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted 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 such files). Yes x No o

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. o

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 o	Accelerated filer x
Non-accelerated filer o	Smaller reporting company o
Emerging growth company o	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of February 28, 2018, based upon the closing price of the common stock as reported by The Nasdaq Capital Market on such date, was approximately $181,050,050. This calculation does not reflect a determination that persons are affiliates for any other purposes.

As of November 14, 2018, 17,420,197 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 2018 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 on Form 10-K.

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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,” “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 Annual Report and elsewhere in this document and 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

As used in this report, each of the terms “we,” “us,” “our,” the “Company” and “Simulations Plus” refers to Simulations Plus, Inc. and its wholly owned subsidiaries Cognigen Corporation, of Buffalo, New York, and DILIsym Services, Inc of Research Triangle Park, North Carolina, 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, and for machine-learning-based prediction of properties of molecules solely from their structure. Our pharmaceutical/chemistry software is licensed to major pharmaceutical, biotechnology, agrochemical, cosmetics, and food industry companies and to regulatory agencies worldwide for use in the conduct of industry-based research. We also provide consulting services ranging from early drug discovery through preclinical and clinical trial data analysis and for submissions to regulatory agencies. Simulations Plus is headquartered in Southern California, with offices in Buffalo, New York, and Research Triangle Park, North Carolina, and its common stock trades on the Nasdaq Capital Market under the symbol “SLP.”

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 are one of only two global companies who provide a wide range of early discovery, preclinical, and clinical consulting services and software. Our innovations in integrating new and existing science in medicinal chemistry, computational chemistry, pharmaceutical science, biology, physiology, and machine learning into our software have made us the leading software provider for PBPK modeling and simulation, prediction of molecular properties from structure, and prediction of drugs to induce liver injury or to treat nonalcoholic fatty liver disease.

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 consulting services to guide early drug discovery (molecule design and screening), preclinical, and clinical 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 designs, and simulate outcomes in special populations, such as the elderly and pediatric patients.

Simulations Plus previously acquired Cognigen Corporation (Cognigen) as a wholly owned subsidiary. Cognigen was originally incorporated in 1992. Through the integration of Cognigen into Simulations Plus, Simulations Plus became also a leading provider of population modeling and simulation contract research services for the pharmaceutical and biotechnology industries. Our clinical-pharmacology-based consulting services include pharmacokinetic and pharmacodynamic modeling, clinical trial simulations, data programming, and technical writing services in support of regulatory submissions. We have also developed software for harnessing cloud-based computing in support of modeling and simulation activities and secure data archiving, and we provide consulting services to improve interdisciplinary collaborations and research and development productivity.

Simulation Plus also acquired DILIsym Services, Inc. (DILIsym) as a wholly owned subsidiary. We believe the combination of Simulations Plus and DILIsym provides substantial future potential based on the complementary strengths of each of the companies. The acquisition of DILIsym positions the Company as the leading provider of Drug Induced Liver Injury (DILI) modeling and simulation software and related scientific consulting services. In addition to the DILIsym® software for analysis of potential drug-induced liver injury, DILIsym Services, Inc. also has developed a simulation program for analyzing nonalcoholic fatty liver disease (NAFLD) called NAFLDsym™. Both the DILIsym and NAFLDsym software programs require outputs from physiologically based pharmacokinetics (PBPK) software as inputs. The GastroPlus™ PBPK software from Simulations Plus provides such information; thus, the integration of these technologies will provide a seamless capability for analyzing the potential for drug-induced liver injury for new drug compounds and for investigating the potential for new therapeutic agents to treat nonalcoholic fatty liver disease.

PRODUCTS

General

We currently offer ten software products for pharmaceutical research and development: five simulation programs that provide time-dependent results based on solving large sets of differential equations: GastroPlus™; DDDPlus™; MembranePlus™; DILIsym®; and NAFLDsym™; three programs that are based on predicting and analyzing static (not time-dependent) properties of chemicals: ADMET Predictor™; MedChem Designer™; and MedChem Studio™ (the combination of ADMET Predictor, MedChem Designer, and MedChem Studio is called our ADMET Design Suite™); a program which is designed for rapid clinical trial data analysis and regulatory submissions called PKPlus™; and a program called KIWI™ from our Cognigen division that provides an integrated platform for data analysis and reporting through our proprietary secure cloud.

GastroPlus™

Our flagship product, originally introduced in 1998, and currently our largest single source of software revenue, is GastroPlus. GastroPlus mechanistically simulates the absorption, pharmacokinetics, pharmacodynamics, and drug-drug interactions of compounds administered to humans and animals and is currently the most widely used commercial software of its type by 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 was 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 the European Union, our participation in this project was at our own expense, while other members were compensated for their work; however, we were a full member with access to all of the data and discussions of all other members. We believe our investment to participate in this initiative enabled us to benefit from, and to contribute to, advancing the prediction of human oral bioavailability from preclinical data, and ensured that we are well-known to member pharmaceutical companies and regulatory agencies.

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. The objective of this agreement was 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 received up to $200,000 per year. This RCA could be renewed for up to a total of three years based on the progress achieved during the project. After a successful second year, the RCA was extended for two additional years in September 2016, with primary tasks completed in September 2018. Additional functionality was further requested by the FDA, and a new funded contract

was awarded for the 2018-19 period.

We were awarded another RCA by the FDA in September 2015; this one to expand the capabilities of GastroPlus to simulate the dosing of long-acting injectable microspheres for both small and large molecules (biologics). This type of dosage form is usually injected via subcutaneous or intramuscular routes. This RCA also provides up to $200,000 per year for up to three years. Under this agreement, we are developing simulation models to deal with the very slow dissolution/decomposition of the microsphere carrier material that gradually releases the active drug over periods as long as weeks or months. After a successful second year, the RCA was renewed for the third year in September 2017 and will be completed in September 2018 unless extended.

In July 2018 we entered into a one-year funded research collaboration with a large European consortium to further develop and validate the mechanistic Transdermal Compartmental Absorption and Transit (TCAT™) model in GastroPlus™. This project will contribute substantially to improvements in the program, specifically directed toward the predictions of local exposure within the skin layer following topical administration of various chemicals. We expect the developments under this agreement will aid companies and regulatory agencies as they strive to implement an animal-free chemical safety assessment program.

In addition to the two funded efforts with the FDA described above, we also have an unfunded RCA with the FDA's Office of Generic Drugs (OGD) that began in 2014. The objective of this RCA, which has a five-year term, is directed toward the FDA's evaluation of mechanistic IVIVCs (*in vitro-in vivo* correlations) to determine whether mechanistic absorption modeling (MAM) can relate laboratory (*in vitro*) dissolution experiment results to the behavior of dosage forms in humans and animals (*in vivo*) better than traditional empirical methods.

In May 2018, we released Version 9.6 of GastroPlus. Version 9.6 is the most feature-rich and user-friendly release in our history. New functionalities that we believe provide the most advanced decision-making tool for preclinical and early clinical trial simulation and modeling analysis available today include:

- New dynamic intestinal fluid options added to the #1-ranked ACAT™ oral absorption model
- New population physiologies for obesity and renal impairment disease states
- Expanded enzyme/transporter distribution information for easier extrapolation across species
- Additional compound model files for standard drug-drug interaction (DDI) substrates & inhibitors
- Upgraded capabilities to all major mechanistic absorption routes, including dermal, pulmonary, ocular, and subcutaneous/intramuscular injections
- Enhanced deconvolution methods for generation of mechanistic *in vitro-in vivo* correlations (IVIVCs)
- Improved output/reporting functions in all simulation modes to facilitate communication across departments and with regulatory agencies
- Significant simulation speed improvements
- Custom template generation for seamless use of GastroPlus to drive DILIsym® SimPops™ liver injury predictions

Our goal with GastroPlus is to integrate the most advanced science into user-friendly software to enable researchers and regulators to perform sophisticated analyses of complex compound behaviors in humans and laboratory animals. Already the most widely used program in the world for physiologically based pharmacokinetics (PBPK), the addition of these new capabilities is expected to expand the user base in the early pharmaceutical research and development process, while also helping us to further penetrate biopharmaceuticals, food, cosmetics, and general toxicology markets.

Version 9.7 is now in development and release is expected in early 2019. This version will add a number of important new capabilities, including improvements to population simulations, dissolution, absorption, PBPK models, and drug-drug interactions, among others.

DDDPlus™

DDDPlus mechanistically simulates *in vitro* (laboratory) experiments that measure the rate of dissolution of a drug as well as, if desired, the additives (excipients) in a particular dosage form (e.g., powder, tablet, capsule, or injectable solids) under a variety of experimental conditions. This unique software program is used by formulation scientists in industry and the FDA to (1) understand the physical mechanisms affecting the disintegration and dissolution rates of various formulations, (2) reduce the number of cut-and-try attempts to design new drug formulations, (3) design *in vitro* dissolution experiments to better mimic *in vivo* (animal and human) conditions, and (4) . Version 5.0 of DDDPlus, which added a number of significant enhancements, was released in April 2016. This version added new formulation types (controlled release bilayer tablet, delayed release coated tablet, and immediate release coated beads), expanded formulation specification options, biorelevant solubilities and surfactant effects on dissolution, tablet compression and disintegration models, links with GastroPlus, and updated licensing. Current improvements in development and testing include new capabilities to simulate *in vitro* dissolution experiments for long-acting

injectable microspheres as part of our work under the FDA-funded grant mentioned above.

Version 6.0 of DDDPlus is in development testing and will offer a series of new capabilities, including:

- simulation of the *in vitro* dissolution of long-acting injectable dosage forms
- simulation of the *in vitro* dissolution of controlled release bead formulations
- new simulation of artificial stomach-duodenum (ASD) experiments
- ability to fit models from precipitation experiments
- new dissolution apparatus models
- improved output reporting

MembranePlus™

Similar to DDDPlus, MembranePlus mechanistically simulates laboratory experiments, but in this case, the experiments are for measuring permeability of drug-like molecules through various membranes, including several different standard cell cultures (Caco-2, MDCK), as well as artificially formulated membranes (PAMPA). The value of such simulations derives from the fact that when the permeabilities of the same molecules are measured in different laboratories using (supposedly) the same experimental conditions, the 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 scientists to better interpret how results from specific experimental protocols can be used to predict permeability in human and animals, which is the ultimate goal.

Version 2.0 of MembranePlus was released in August 2017. This version added:

- simulation of sandwich hepatocyte assays
- simulation of suspended hepatocyte assays
- intracellular protein binding
- integration of ADMET Predictor metabolism predictions
- improved output reporting

PKPlus™

In August 2016, we released a standalone software product called PKPlus, based on the internal PKPlus Module in GastroPlus that has been available since 2000. The PKPlus Module in GastroPlus provides quick and easy fitting of compartmental pharmacokinetic (PK) models as well as a simple noncompartmental analysis (NCA) for intravenous and extravascular (oral, dermal, ocular, pulmonary, etc.) doses; however, the PKPlus Module in GastroPlus was not designed to meet all of the requirements for performing these analyses for Phase 2 and 3 clinical trials, nor to produce report-quality output for regulatory submissions. The standalone PKPlus program provides the full level of functionality needed by pharmaceutical industry scientists to perform the analyses and generate the outputs needed to fully satisfy regulatory agency requirements for both more complex NCA as well as compartmental PK modeling. After receiving considerable feedback on version 1.0, we began modifying the program to include a number of additional features requested by our users and potential users for release in version 2.0.

PKPlus version 2.0 was released in February 2018. This new version incorporates a wide variety of requested features from current users as well as evaluators of version 1.0, including:

- Ability to edit input data prior to incorporating it into a Project database
- 21 CFR Part 11 compliance for audit trail and validation
- Validation data sets included
- Compartmental multi-dose simulations
- Command-line capability for rapid validation after installation on customers' computers and for batch processing
- Nonparametric superposition for analysis of multiple-dose pharmacokinetics
- New statistics graphical outputs
- Ability to save templates for various types of analyses – reduces time required when working with new datasets

ADMET Predictor™

ADMET (Absorption, Distribution, Metabolism, Excretion, and Toxicity) Predictor is a chemistry-based computer program that takes molecular structures (i.e., drawings of molecules represented in various formats) as inputs and predicts approximately 150 different properties for them at an average rate of over 100,000 compounds per hour on a modern laptop computer. This capability allows chemists to generate estimates for a large number of important molecular properties without the need to synthesize and test the molecules, as well as 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 only 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 multiple peer-reviewed, independent comparison studies for many years, while generating its results at a very 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 typically the majority of a virtual chemical library) before synthesizing and testing them. Thus, millions of virtual 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.

The optional ADMET Modeler™ Module in ADMET Predictor enables scientists to use their own experimental data to quickly create proprietary high-quality predictive models using the same powerful artificial intelligence (AI) engine 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, generating 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 machine-learning/AI models with minimal training.

We released version 8.1 of ADMET Predictor in January 2017. This release included:

- both 64-bit and 32-bit executables, making it possible to handle larger data sets
- optimization of spreadsheet and model-building functions to improve efficiency
- streamlined and much more efficient model-building in ADMET Modeler using our proprietary machine-learning engine
- combinatorial substituent and scaffold replacement operations in the MedChem Studio Module
- new in silico Ames tests to produce reliable confidence predictions that are more broadly applicable
- our proprietary ADMET Risk™ scores accessible graphically in histograms

Version 8.5 was released in November 2017, adding:

- a new Simulation Module to predict absorption and bioavailability for libraries of molecules from their structure
- ability to optimize doses to achieve desired steady-state concentrations
- new property models for rat fraction unbound in plasma, blood/plasma concentration ratio, and metabolism by certain enzymes
- all MedChem Studio features now available through the same graphical user interface as ADMET Predictor
- new synthetic difficulty model
- improved visualization
- multithreading and other speed enhancements

Version 9.0 was released in June 2018, adding:

- Additional pharmacokinetic (PK) endpoint predictions included with the High-Throughput Pharmacokinetics (HTPK) Simulation Module
- New artificial intelligence (machine-learning) models to predict major clearance mechanisms
- Novel DELTA Model™ approach extends model coverage space adding client data through the ADMET Modeler Module

- Multi-class classification models can now be built using our advanced artificial neural network ensemble (ANNE) methodology
- Intuitive graphical display of Biopharmaceutical Classification System (BCS) and Developability Classification System (DCS)
- Rebuilt most classification models to improve their confidence estimates
- New functionality for easily generating and visualizing fingerprints within the MedChem Studio Module

We have made significant investments in two key areas with version 9: improving integration of our top-ranked ADMET Predictor and GastroPlus models to leverage our novel 'Discovery PBPK' approaches for chemists, and further enhancing our best-in-class AI engine to assist with drug discovery. Recent publications from a large pharmaceutical company describing how they have leveraged our 'Discovery PBPK' methods to guide lead optimization illustrate how our unique offerings provide substantial value in this space.

Potential new markets for artificial intelligence (machine learning)

We are currently investigating applications of our sophisticated artificial intelligence (machine-learning) engine outside of our normal pharmaceutical markets. To date, we have conducted several proof-of-concept studies including: (1) predicting missile aerodynamic force and moment coefficients as a function of missile geometry, Mach number, and angle of attack, (2) classifying/identifying missiles and other objects from radar tracking data, (3) mapping jet engine compressor performance to predict when maintenance might be required, and (4) 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 primarily in these areas.

We believe our proprietary AI/machine-learning software engine has a wide variety of potential applications and we intend to pursue funding to develop customized tools to further monetize our investment in this technology by expanding our markets beyond the life sciences and chemistry. In addition, we are examining a variety of expanded capabilities to add to the basic modeling engine to accommodate even larger data sets ("big data analytics") and new applications.

MedChem Designer™

MedChem Designer was initially a molecule-drawing program, or "sketcher", but now has capabilities far 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 provided for free. Our free version includes a small set of ADMET Predictor's 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 approximately 150 predictions that are available. Over 26,500 copies of MedChem Designer have been downloaded by scientists around the world to date.

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 approximately 150 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 each of 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. 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 7), the molecule is not likely to be successful as a drug. The default rules can be modified and new rules can be added by the user to include any desired rule set based on any combination of calculated molecular descriptors, predicted properties, and user inputs. 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.

MedChem Studio™

MedChem Studio has been integrated into the ADMET Predictor platform but can still be licensed separately without requiring a license for ADMET Predictor. MedChem Studio is a powerful software 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 large chemical libraries to find molecules that contain identified substructures, and it enables rapid identification of clusters (classes) of molecules that share common substructures. We have now merged MedChem Studio with ADMET Predictor so that either program can be entered through the same interface, and the communication between the two programs is enhanced through the seamless integration of both technologies. We believe this will enhance the attractiveness of both ADMET Predictor and MedChem Studio to medicinal and computational chemists.

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) very large numbers 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 (the combination of 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 common part of their structures) 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 predicted to be both active against the target and acceptable in a variety of ADMET properties. We demonstrated the power of the ADMET Design Suite during two NCE (new chemical entity) projects wherein we designed lead molecules to inhibit the growth of the plasmodium falciparum malaria parasite in one study, and lead molecules that were able to inhibit two targets at the same time: COX-1 and COX-2. In each case, we announced ahead of time that we were attempting to do this, and we reported the results when the projects were complete. Every molecule we designed and had synthesized hit their targets in both projects, clearly demonstrating the power of the ADMET Design Suite.

KIWI™

Drug development programs rely increasingly on modeling and simulation analyses to support decision-making and submissions to regulatory agencies. To ensure high-quality analyses, organizations must not only apply high-quality science, but must also be able to support the science by being able to validate the results. KIWI is a cloud-based web application that was developed to efficiently organize, process, maintain, and communicate the volume of data and results generated by pharmacologists and scientists over the duration of a drug development program. The validated workflow and tools within KIWI promote traceability and reproducibility of results.

The pharmaceutical industry has been rapidly adopting cloud technology as a solution to ever-expanding computer processing needs. Leveraging our 20-plus years of experience in providing an architecture supporting modeling and simulation efforts, we have developed KIWI as a secure, validated, enterprise-scale environment, enabling global teams to collaborate on model-based decision making. KIWI has proven to be a valuable platform for encouraging interdisciplinary discussions about the model development process and interpretation of results. We continue to receive positive feedback about the functionality implemented in KIWI and the value of the approach we have taken to harness cloud technology. We continue to improve functionality and collaboration within the KIWI platform, and we expect the licensing fee will be a source of recurring revenue for further development and growth. KIWI Version 1.3 was released in May 2015. This version of KIWI provided our user community with access to new features that accelerated completion of modeling projects by decreasing run times and facilitating the comparison and exporting of results across models. These features included dynamic comparisons of model parameter estimates and diagnostic plots, export of model run records for regulatory submissions, and accelerated infrastructure with the upgrade to the latest versions of NONMEM® and Perl-speaks-NONMEM running in a 64-bit Linux environment.

KIWI Version 1.6 was released in September 2016. This version introduced major enhancements in the functionality of visualization tools offered by the platform. These enhancements include simplifying the creation of plots and comparing them across multiple models, thus accelerating the model refinement process. In addition, analysts could now conveniently copy visualization preferences across projects, improving consistency and facilitating collaboration and communication with clients and colleagues.

KIWI 2 was released in December 2017. This latest version introduces a repository within the KIWI Cloud service to facilitate the management and organization of data and documents used and produced to support the modeling and simulation analyses used, in part, to submit new drug applications. The user interface provides a predefined directory as a default that can be customized, allows file version control, and provides a comprehensive roles and permissions structure to enhance collaboration among a community of users. As part of this initiative, an enhanced authentication framework foundation was included to provide the ability for clients to customize authentication rules according to their internal regulatory policies and procedures. In addition, since it can take hundreds of models to create one final model, an automated diagnostics dashboard has been added that visually displays the results of over 10 diagnostics that are used by modelers to decide what direction to take their modeling with the potential to significantly reduce the amount of time it takes to arrive at a final model.

KIWI 3.0 was released in August, 2018. The latest version incorporates ExploreLive and Explore, two powerful new visualization modules, introduced for exploratory data analysis of information stored in analysis datasets and NONMEM outputs. In addition, new automated diagnostics are now performed for every NONMEM run, visually reported in the Summarize module. KIWI version 3.0 also features improved infrastructure and security, as well as a completely redesigned Knowledge Portal used to access the KIWI program.

We continue enhancing KIWI as part of our five-year, almost-$5 million contract with the Bill and Melinda Gates Foundation.

DILIsym

The DILIsym software is a quantitative systems pharmacology (QSP) program that has been in development since 2011. QSP software models are based on the fundamental understanding of complex biological pathways, disease processes, and drug mechanisms of action, integrating information from experiments and forming hypotheses for the next experimental model. DILIsym deals with the propensity for some drug molecules to induce temporary or permanent changes in biological functions within liver cells (hepatocytes) that can result in damage to the liver. Some drugs cause temporary changes in liver function but the body soon compensates and liver function returns to normal. Other drugs cause liver function to permanently decline as they continue to be taken. The DILIsym software models a variety of interactions within the hepatocytes to determine whether a particular drug molecule interrupts normal signaling pathways in a manner to induce injury to the cells.

Version 7A of the DILIsym software was released in January 2018. This version changes the software from an open-source platform to a secure executable that incorporates new proprietary code enabling tighter integration with our GastroPlus PBPK software. Securing the code is necessary to ensure that results are consistent across all users to assure regulatory agencies that the calculated results are from a validated version. Open source programs are subject to modification by the user and so each use could have a different set of calculations, so validation would not be assured. In addition, a number of important new capabilities were added:

- Additional validation compounds
- New optimization interface allowing complex fitting using genetic algorithms
- Clinical Monitoring feature allowing dynamic clinical trials with dose alterations based on specified thresholds
- Weight-adjusted dosing option
- Export enhancements providing better information on simulation setup within exported Excel® file
- MATLAB 2017b friendly – faster simulations
- Two new SimPops
  - Combined ALT biomarker parameter variability with toxicity pathway parameters
  - Mitochondrial biogenesis parameter variability
- Creation of custom cohorts from existing SimPops/SimCohorts
  - Updated initial conditions infrastructure allowing importing custom SimPops in compiled version
- Update Output Table with more clinically important metrics built-in

NAFLDsym

Where DILIsym is used to investigate the likelihood that a known drug molecule would cause injury to the liver, NAFLDsym is concerned with a liver that is already diseased by excess fat and investigates the likelihood that various molecules might provide beneficial therapeutic benefits to treat or cure the disease. DILIsym can be considered a “shrink wrap” software product, usable across many companies and drug development projects. NAFLDsym, on the other hand, requires modification for each of a number of different mechanisms of action that potential new drug compounds could use to treat the disease, and so is a customized tool used in consulting projects for each new client project. NAFLDsym version 2A will be released for licensing and consulting use in October of 2018. The software now includes the three most important components of NAFLD/NASH: steatosis, inflammation, and fibrosis.

RENAsym

Where DILIsym is used to investigate the likelihood that a known drug molecule would cause injury to the liver, RENAsym will be focused on investigating and predicting drug-induced kidney injury, or acute kidney injury (AKI). RENAsym will be another “shrink wrap” software product, usable across many companies and drug development projects. The software will utilize predictions of drug exposure in the kidney from PBPK platforms such as GastroPlus, along with in vitro data related to certain kidney injury mechanisms, to make predictions. The first expected release of RENAsym will be available in Fall of 2020. The initial development is being funded via an NIH small business grant.

Contract Research and Consulting Services

Our scientists and engineers have expertise in drug absorption via various dosing routes (oral, intravenous, subcutaneous, intramuscular, ocular, nasal/pulmonary, and dermal), pharmacokinetics, pharmacodynamics, and drug-drug interactions. They have attended over 200 scientific meetings worldwide in the past four years, often speaking and presenting. We conduct contracted consulting studies for large customers (including many of the top twenty 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 consulting teams to meet the increased workload.

Currently we are approximately half way through the work on a five-year consulting agreement with the Bill and Melinda Gates Foundation to implement a platform for coordinating the data generated by global teams engaged in model-based drug development.

We are also currently working with the FDA on three Research Collaboration Agreements (RCAs): the funded efforts for long-acting injectable microspheres/ocular dosing and the unfunded IVIVC effort, both described above under “GastroPlus”.

We have a reputation for high-quality analyses and regulatory reporting of data collected during preclinical experiments as well as clinical trials of new and existing pharmaceutical products, typically working on 80-100 drug projects per year. Traditionally, the model-based analysis of clinical trial data was different from the modeling analysis offered by GastroPlus; the former relied more on statistical and semi-mechanistic models, whereas the latter is based on very detailed mechanistic models. Statistical models rely on direct observation and mathematical equations that are used to fit data collected across multiple studies along with describing the variability within and between patients. Mechanistic models are based on a detailed understanding of the human body and the chemistry of the drug and involve deep mathematical and scientific representation of the phenomena involved in drug dissolution/precipitation, absorption, distribution, metabolism, and elimination. Collectively, the models guide drug formulation design and dose selection. Beginning in 2014, the U.S. F.D.A and other regulatory agencies began to emphasize the need to push mechanistic PBPK modeling and simulation into clinical pharmacology, and we have seen the benefit of having our clinical pharmacology team in the Cognigen division and our scientists in our Lancaster, California (Simulations Plus) division working together to achieve this goal.

PRODUCT DEVELOPMENT

Development of our software is focused on expanding product lines, designing enhancements to our core technologies, and integrating existing and new products into our principal software architecture and platform technologies. 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 Dassault Systèmes Americas Corp. (formerly known as Accelrys, Inc.), a San Diego division of Dassault Systemes in France, pursuant to which a small royalty is paid to Dassault Systèmes Americas Corp. from revenues on each license for the Metabolism 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. (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 nonassertion 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. All payments were made as of April 2017. The total consideration is being amortized at a constant rate of $150,000 per quarter until it is completely amortized, after which no further expense will be incurred. To date, this has resulted in expense savings over $1,300,000 compared to 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, Taiwan, Korea, 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 reported research was performed using our software. Many of these presentations are from industry and FDA scientists; some are from our staff. In addition, more than 100 peer-reviewed scientific journal articles, posters, and podium presentations are typically published each year using our software, mostly by our customers, further supporting its use in a wide range of preclinical and clinical studies.

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 trainings both online 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 consulting scientists who can answer a wide range of in-depth technical questions about methods and features; (2) our scientists and engineers gain an appreciation for the customer's environment and problems; 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 independent distributors in Japan, China, India, and Korea who also sell and market our products with support from our scientists and engineers.

We provide support to the GastroPlus User Group in Japan, which was organized by Japanese researchers in 2009. In early 2013, a group of scientists in Europe and North America organized another GastroPlus User Group following the example set in Japan. Over 1,000 members have joined this group to date. We support this group through coordination of online meetings each month and managing the user group web site for exchange of information among members. These user groups provide us valuable feedback with respect to desired new features and suggested interface changes.

PRODUCTION

Our pharmaceutical software products are designed and developed by our development teams in California, North Carolina (Research Triangle Park), and New York (Buffalo), we also employee people who are able to work remotely using collaboration software. Our products and services are now delivered electronically – we no longer provide CD-ROMs and printed manuals or reports.

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 flagship product, GastroPlus, is the most widely used commercial PBPK modeling platform and has one significant competitor; others could be developed over time, but with the high barrier to entry, it would be difficult to validate new software to levels required to support regulatory submissions. Our PKPlus software product will compete with one major and a few minor software programs. 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. We believe DILIsym and NAFLDsym enjoy a unique market position, with no significant competition.

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 and scientific consulting service providers, but also with the in-house development and scientific consulting teams at some of the larger pharmaceutical companies.

Although competitive products exist, both new licenses and license renewals for GastroPlus have continued to grow. We believe that we enjoy a dominant market share in this segment. We believe our ADMET Predictor/ADMET Modeler, MedChem Studio, MedChem Designer, DDDPlus, MembranePlus, PKPlus, KIWI, DILIsym, and NAFLDsym software offerings are each unique in their combination of capabilities and we intend to continue to market them aggressively.

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) continue to attract and retain a highly skilled scientific and engineering team, (5) aggressively promote our products and services to our global market, and (6) develop and maintain relationships with research and development departments of pharmaceutical companies, universities, and government agencies.

In addition, we actively seek strategic acquisitions to expand the pharmaceutical software and services business.

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 teams and our inside sales and support staff via telephone, e-mail and web-based support for all of our pharmaceutical software products worldwide. Technical support for pharmaceutical software products sales is minimal, averaging a few person-hours per month.

We provide free telephone, e-mail and web-based support for all of our pharmaceutical software products worldwide from our offices in the U.S. Technical support for pharmaceutical software is provided by our life sciences teams and our inside sales and support staff. Technical support for pharmaceutical software products is generally minimal, averaging a few person-hour product sale.

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 $3,936,000 during fiscal year 2018, of which $2,145,000 was capitalized. R&D expenditures were approximately $2,743,000 during fiscal year 2017, of which $1,376,000 was capitalized. R&D expenditures during fiscal year 2016 were approximately $2,641,000, of which $1,196,000 was capitalized.

CUSTOMERS

Our customers include large, medium-sized and smaller biotech and pharmaceutical companies, universities, and regulatory agencies and other government organizations. We concentrate on serving the needs of our customers in drug discovery, development, clinical trials, and post-patent generic formulation development. Our current customer base is highly fragmented, in 2018 one of our customers was 9% of our revenues, with that exception of no other customer customers made up more than 7% of our revenues in the last 3 years.

SEASONALITY

We have traditionally experienced seasonal revenue weakness during our fiscal fourth quarter (June-August) due to summer vacations and reduced activities at our customers' sites. Though our net sales figures for any quarter are not necessarily indicative of sales for any future period, our pharmaceutical software is typically licensed on an annual basis which means renewals usually fall in the same quarter year after year.

ENVIRONMENTAL MATTERS

We believe we are in compliance in all material respects with all applicable environmental laws. Presently, we do not anticipate that such compliance will have a material effect on capital expenditures, earnings or competitive position with respect to any of our operations.

EMPLOYEES

As of August 31, 2018, Simulations Plus and its subsidiaries Cognigen Corporation and DILIsym, employed a total of 95 persons, including 93 full-time employees and 2 part-time employees, consisting of 69 in technical and research and development, 7 in marketing and sales, and 19 in administration and accounting. Currently 45 employees hold Ph.Ds. in their respective science or engineering disciplines, and 18 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 primarily protect our intellectual property through copyrights and trade secrets. 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

You should carefully consider the risks described below before investing in our publicly traded securities. The risks described below are not the only ones facing us. Our business is also subject to the risks that affect many other companies, such as competition, technological obsolescence, labor relations, general economic conditions, geopolitical changes, and international operations. We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. Additional risks not currently known to us or that we currently believe are immaterial also may impair our business operations and our liquidity. The risks described below could cause our actual results to differ materially from those contained in the forward-looking statements we have made in this Annual Report on Form 10-K, the information incorporated herein by reference, and those forward-looking statements we may make from time to time. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties.

Certain Risks Related to Our Marketplace and Environment

Our ability to sustain or increase revenues will depend upon our success in entering new markets, continuing to increase our customer base, and in deriving additional revenues from our existing customers.

Our products are currently used primarily by molecular modeling and simulation specialists in pharmaceutical, biotechnology, agrotech, cosmetics, and government research organizations. One component of our overall business strategy is to derive more revenues from our existing customers by expanding their use of our products and services. Such strategy would have our customers utilize our scientific informatics platforms and our tools and components to

leverage vast amounts of information stored in both corporate databases and public data sources in order to make informed scientific and business decisions during the research and development process. In addition, we seek to expand into new markets, and new areas within our existing markets, by acquiring businesses in these markets, attracting and retaining personnel knowledgeable in these markets, identifying the needs of these markets, and developing marketing programs to address these needs. If successfully implemented, these strategies would increase the usage of our software and services by biologists, chemists, engineers, and informaticians operating within our existing pharmaceutical, biotechnology, and chemical customers, as well as by new customers in other industries. However, if our strategies are not successfully implemented, our products and services may not achieve market acceptance or penetration in targeted new departments within our existing customers or in new industries. As a result, we may incur additional costs and expend additional resources without being able to sustain or increase revenue.

Consolidation within the pharmaceutical and biotechnology industries may continue to lead to fewer potential customers for our products and services.

A significant portion of our customer base consists of pharmaceutical and biotechnology companies. Consolidation within the pharmaceutical and biotechnology industries may result in fewer customers for our products and services. Although the industry consolidation that has taken place over the past 20 years has not prevented our business from growing to date, if one of the parties to a consolidation uses the products or services of our competitors, we may lose existing customers as a result of such consolidation.

Increasing competition and increasing costs within the pharmaceutical and biotechnology industries may affect the demand for our products and services, which may affect our results of operations and financial condition.

Our pharmaceutical and biotechnology customers' demand for our products is impacted by continued demand for their products and by our customers' research and development costs. Demand for our customers' products could decline, and prices charged by our customers for their products may decline, as a result of increasing competition, including competition from companies manufacturing generic drugs. In addition, our customers' expenses could continue to increase as a result of increasing costs of complying with government regulations and other factors. A decrease in demand for our customers' products, pricing pressures associated with the sales of these products and additional costs associated with product development could cause our customers to reduce research and development expenditures. Although our products increase productivity and reduce costs in many areas, because our products and services depend on such research and development expenditures, our revenues may be significantly reduced.

Health care reform and restrictions on reimbursement may affect the pharmaceutical, biotechnology, and industrial chemical companies that purchase or license our products or services, which may affect our results of operations and financial condition.

The continuing efforts of government and third-party payers in the markets we serve to contain or reduce the cost of health care may reduce the profitability of pharmaceutical, biotechnology, and industrial chemical companies, causing them to reduce research and development expenditures. Because some of our products and services depend on such research and development expenditures, our revenues may be significantly reduced. We cannot predict what actions federal, state, or private payers for health care goods and services may take in response to any health care reform proposals or legislation.

We face strong competition in the life science market for computer-aided design modeling and simulation software and for cheminformatics products.

The market for our computer-aided design modeling and simulation software products for the life science market is intensely competitive. We currently face competition from other scientific software providers, larger technology and solutions companies, in-house development by our customers and academic and government institutions, and the open source community. Some of our competitors and potential competitors have longer operating histories in certain segments of our industry than we do and could have greater financial, technical, marketing, research and development, and other resources. Many of our competitors offer products and services directed at more specific markets than those we target, enabling these competitors to focus a greater proportion of their efforts and resources on these markets. Some offerings that compete with our products are developed and made available at lower cost by government organizations and academic institutions, and these entities may be able to devote substantial resources to product development and also offer their products to users for little or no charge. We could also face competition from open

source software initiatives, in which developers provide software and intellectual property free over the Internet. In addition, some of our customers spend significant internal resources in order to develop their own software. Moreover, we intend to leverage our scientific informatics platform in order to enable our customers to more effectively utilize the vast amounts of information stored in both their databases and public data sources in order to make informed scientific and business decisions during the research and development process. This strategy could lead to competition from much larger companies that provide general data storage and management software. There can be no assurance that our current or potential competitors will not develop products, services, or technologies that are comparable to, superior to, or render obsolete, the products, services, and technologies we offer. There can be no assurance that our competitors will not adapt more quickly than we to technological advances and customer demands, thereby increasing such competitors' market share relative to ours. Any material decrease in demand for our technologies or services may have a material adverse effect on our business, financial condition, and results of operations.

We are subject to pricing pressures in some of the markets we serve.

The market for computer-aided design modeling and simulation products for the life science industry is intensely competitive. Although the average price of our software licenses has increased slightly or remained relatively constant for fiscal 2016, 2017, and 2018, we may experience a decline in the future. In response to increased competition and general adverse economic conditions in this market, we may be required to modify our pricing practices. Changes in our pricing model could adversely affect our revenue and earnings.

Our operations may be interrupted by the occurrence of a natural disaster or other catastrophic event at our primary facilities.

Our research and development operations and administrative functions are primarily conducted at our facilities in Lancaster, California, Buffalo, New York and Research Triangle Park, North Carolina. Although we have contingency plans in effect for natural disasters or other catastrophic events, the occurrence of such events could still disrupt our operations. For example, our Lancaster, California facility is located in a state that is particularly susceptible to earthquakes. Any natural disaster or catastrophic event in our facilities or the areas in which they are located could have a significant negative impact on our operations.

Our insurance coverage may not be sufficient to avoid material impact on our financial position or results of operations resulting from claims or liabilities against us, and we may not be able to obtain insurance coverage in the future.

We maintain insurance coverage for protection against many risks of liability. The extent of our insurance coverage is under continuous review and is modified as we deem it necessary. Despite this insurance, it is possible that claims or liabilities against us may have a material adverse impact on our financial position or results of operations. In addition, we may not be able to obtain any insurance coverage, or adequate insurance coverage, when our existing insurance coverage expires. For example, we do not carry earthquake insurance for our facilities in Lancaster, California, because we do not believe the costs of such insurance are reasonable in relation to the potential risk for our part of California.

Changes in government regulation or in practices relating to the pharmaceutical or biotechnology industries, including potential health care reform, could decrease the need for the services we provide.

Governmental agencies throughout the world, but particularly in the U.S., strictly regulate the drug development process. Our business involves helping pharmaceutical and biotechnology companies, among others, navigate the regulatory drug approval process. Accordingly, many regulations, and often new regulations, are expected to result in higher regulatory standards and often additional revenues for companies that service these industries. However, some changes in regulations, such as a relaxation in regulatory requirements or the introduction of streamlined or expedited drug approval procedures, or an increase in regulatory requirements that we have difficulty satisfying or that make our services less competitive, could eliminate or substantially reduce the demand for our services.

Any negative commentaries made by any regulatory agencies or any failure by us to comply with applicable regulations and related guidance could harm our reputation and operating results, and compliance with new

regulations and guidance may result in additional costs.

Any negative commentaries made by any regulatory agencies or any failure on our part to comply with applicable regulations could result in the termination of ongoing research or the disqualification of data for submission to regulatory authorities. This could harm our reputation, our prospects for future work, and our operating results. If our operations are found to violate any applicable law or other governmental regulations, we might be subject to civil and criminal penalties, damages, and fines. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, and damage our reputation.

Many of our contracts are fixed-price and may be delayed or terminated or reduced in scope for reasons beyond our control, or we may underprice or overrun cost estimates with these contracts, potentially resulting in financial losses.

Many of our contracts provide for services on a fixed-price or fee-for-service with a cap basis and, accordingly, we bear the financial risk if we initially underprice our contracts or otherwise overrun our cost estimates. In addition, these contracts may be terminated or reduced in scope either immediately or upon notice. Cancellations may occur for a variety of reasons, and often at the discretion of the client. The loss, reduction in scope, or delay of a large contract or the loss or delay of multiple contracts could materially adversely affect our business, although our contracts frequently entitle us to receive the costs of winding down the terminated projects, as well as all fees earned by us up to the time of termination. Some contracts also entitle us to a predetermined termination fee and irrevocably committed costs/expenses.

We could experience a breach of the confidentiality of the information we hold or of the security of our computer systems.

We operate large and complex computer systems that contain significant amounts of client data. As a routine element of our business, we collect, analyze, and retain substantial amounts of data pertaining to the clinical study data analysis we conduct for our clients. Unauthorized third parties could attempt to gain entry to such computer systems for the purpose of stealing data or disrupting the systems. We believe that we have taken appropriate measures to protect them from intrusion, and we continue to improve and enhance our systems in this regard, but in the event that our efforts are unsuccessful, we could suffer significant harm. Our contracts with our clients typically contain provisions that require us to keep confidential the information generated from these studies. In the event the confidentiality of such information was compromised, we could suffer significant harm.

Impairment of goodwill or other intangible assets may adversely impact future results of operations.

We have intangible assets, including goodwill and other indefinite-lived intangibles, on our balance sheet due to our acquisitions of businesses. The initial identification and valuation of these intangible assets and the determination of the estimated useful lives at the time of acquisition involve use of management judgments and estimates. These estimates are based on, among other factors, input from accredited valuation consultants, reviews of projected future income cash flows and statutory regulations. The use of alternative estimates and assumptions might have increased or decreased the estimated fair value of our goodwill and other intangible assets that could potentially result in a different impact to our results of operations. If the future growth and operating results of our business are not as strong as anticipated and/or our market capitalization declines, this could impact the assumptions used in calculating the fair value of goodwill or other indefinite-lived intangibles. To the extent goodwill or other indefinite-lived intangibles are impaired, their carrying value will be written down to its implied fair value and a charge will be made to our income from continuing operations. Such an impairment charge could materially and adversely affect our operating results. As of August 31, 2018, the carrying amount of goodwill and other intangibles was $10,387,198 on our consolidated balance sheet.

Certain Risks Related to Our Operations

Software Defects or malfunctions in our products could hurt our reputation among our customers, result in delayed or lost revenue, and expose us to liability.

Our business and the level of customer acceptance of our products depend upon the continuous, effective, and reliable operation of our software and related tools and functions. To the extent that defects cause our software to malfunction

and our customers' use of our products is interrupted, our reputation could suffer and our revenue could decline or be delayed while such defects are remedied. We may also be subject to liability for the defects and malfunctions of third-party technology partners and others with whom our products and services are integrated.

Delays in the release of new or enhanced products or services or undetected errors in our products or services may result in increased cost to us, delayed market acceptance of our products, and delayed or lost revenue.

To achieve market acceptance, new or enhanced products or services can require long development and testing periods, which may result in delays in scheduled introduction. Any delays in the release schedule for new or enhanced products or services may delay market acceptance of these products or services and may result in delays in new customer orders for these new or enhanced products or services or the loss of customer orders. In addition, new or enhanced products or services may contain a number of undetected errors or “bugs” when they are first released. Although we extensively test each new or enhanced software product or service before it is released to the market, there can be no assurance that significant errors will not be found in existing or future releases. As a result, in the months following the introduction of certain releases, we may need to devote significant resources to correct these errors. There can be no assurance, however, that all of these errors can be corrected.

We are subject to risks associated with the operation of a global business.

We derive a significant portion of our total revenue from our operations in international markets. During the years ended August 31, 2018, 2017 and 2016, 39%, 38% and 38% respectively, of our total revenue was derived from our international operations. Our global business may be affected by local economic conditions, including inflation, recession, and currency exchange rate fluctuations. In addition, political and economic changes, including international conflicts, including terrorist acts, throughout the world may interfere with our or our customers' activities in particular locations and result in a material adverse effect on our business, financial condition, and operating results. Potential trade restrictions, exchange controls, adverse tax consequences, and legal restrictions may affect the repatriation of funds into the U.S. Also, we could be subject to unexpected changes in regulatory requirements, the difficulties of compliance with a wide variety of foreign laws and regulations, potentially negative consequences from changes in or interpretations of US and foreign tax laws, import and export licensing requirements, and longer accounts receivable cycles in certain foreign countries. These risks, individually or in the aggregate, could have an adverse effect on our results of operations and financial condition. For example, we are subject to compliance with the U.S. Foreign Corrupt Practices Act and similar anti-bribery laws, which generally prohibit companies and their intermediaries from making improper payments to foreign government officials for the purpose of obtaining or retaining business. While our employees, distributors, and agents are required to comply with these laws, we cannot be sure that our internal policies and procedures will always protect us from violations of these laws despite our commitment to legal compliance and corporate ethics. The occurrence or allegation of these types of risks may adversely affect our business, performance, prospects, value, financial condition, and results of operations.

The drug discovery and development services industry is highly competitive.

Our clinical pharmacology division often competes for business not only with other clinical research organization (CROs), but also with internal discovery and development departments within our larger clients, who may have greater resources than ours. We also compete with universities and teaching hospitals for outsourced services. We compete based on a variety of factors, including:

- reputation for on-time quality performance;
- reputation for regulatory compliance;
- expertise and experience in multiple specialized areas;
- scope and breadth of service and product offerings across the drug discovery and development spectrum;
- ability to provide flexible and customized solutions to support our clients' drug discovery and development needs;
- price/value;
- technological expertise and efficient drug development processes;
- financial stability;
- accessibility of client data through secure portals; and
- ability to acquire, process, analyze, and report data in an accurate manner.

If we do not compete successfully, our business could suffer. Increased competition might lead to price and other concessions that might adversely affect our operating results. The drug discovery and development services industry has continued to see a trend towards consolidation, particularly among biotechnology companies, who are targets for each other and for larger pharmaceutical companies. If this trend continues, it is likely to produce more competition among the larger companies and CROs generally, with respect to both clients and acquisition candidates. In addition, while there are substantial barriers to entry for large, global competitors with broad-based services, small, specialized entities considering entering the CRO industry will continue to find lower barriers to entry, and private equity firms may determine that there are opportunities to acquire and consolidate these companies, thus further increasing possible competition. More generally, our competitors or others might develop technologies, services, or products that are more effective or commercially attractive than our current or future technologies, services, or products, or that render our technologies, services, or products less competitive or obsolete. If competitors introduce superior technologies, services, or products and we cannot make enhancements to ours to remain competitive, our competitive position, and in turn our business, revenue, and financial condition, would be materially and adversely affected. In the aggregate, these competitive pressures may affect the attractiveness of our technologies, services, or products and could adversely affect our financial results.

Potential Changes in U.S. and International Tax Law.

In the U.S., there are several proposals to reform corporate tax law that are currently under consideration. These proposals include reducing the corporate statutory tax rate, broadening the corporate tax base through the elimination or reduction of deductions, exclusions, and credits, implementing a territorial regime of taxation, limiting the ability of U.S. corporations to deduct interest expense associated with offshore earnings, modifying the foreign tax credit rules, and reducing the ability to defer U.S. tax on offshore earnings. These or other changes in the U.S. tax laws could increase our effective tax rate, which would affect our profitability.

Contract research services create a risk of liability.

As a CRO, we face a range of potential liabilities which may include:

- Errors or omissions in reporting of study detail in preclinical studies that may lead to inaccurate reports, which may undermine the usefulness of a study or data from the study, or which may potentially advance studies absent the necessary support or inhibit studies from proceeding to the next level of testing; and

- Risks associated with our possible failure to properly care for our clients' property, such as research models, records, work in progress, or other archived materials.

Contractual risk transfer indemnifications generally do not protect us against liability arising from certain of our own actions, such as negligence or misconduct. We could be materially and adversely affected if we are required to pay damages or bear the costs of defending any claim that is outside any contractual indemnification provision, or if a party does not fulfill its indemnification obligations, or the damage is beyond the scope or level of insurance coverage. We also often contractually indemnify our clients (subject to a limitation of liability), similar to the way they indemnify us, and we may be materially adversely affected if we have to fulfill our indemnity obligations. Furthermore, there can be no assurance that we nor a party required to indemnify us will be able to maintain such insurance coverage (either at all or on terms acceptable to us).

Upgrading our software could result in implementation issues and business disruptions.

In recent years we implemented a project to refactor our software programs. In doing so we face the possibility that existing users will find the software unacceptable, or new users may not be as interested as they have been in the past versions. Translation errors might introduce new software bugs that will not be caught.

The drug discovery and development industry has a history of patent and other intellectual property litigation, and we might be involved in costly intellectual property lawsuits.

The drug discovery and development industry has a history of patent and other intellectual property litigation and these lawsuits will likely continue. Accordingly, we face potential patent infringement suits by companies that have patents for similar products and methods used in business or other suits alleging infringement of their intellectual property rights. Legal proceedings relating to intellectual property could be expensive, take significant time and divert management's attention from other business concerns, whether we win or lose. If we do not prevail in an infringement lawsuit brought against us, we might have to pay substantial damages, including treble damages, and we could be required to stop the infringing activity or obtain a license to use technology on unfavorable terms.

We may not be able to successfully develop and market new services and products.

We may seek to develop and market new services and products that complement or expand our existing business or service offerings. We cannot guarantee that we will be able to identify new technologies of interest to our customers. Even if we are able to identify new technologies of interest, we may not be able to negotiate license agreements on acceptable terms, or at all. If we are unable to develop new services and products and/or create demand for those newly developed services and products, our future business, results of operations, financial condition, and cash flows could be adversely affected.

Ability to incur debt could adversely affect our business and growth prospects.

At August 31, 2018, we had no borrowed debt and have no need to do so to fund normal operations in the foreseeable future; however, should circumstances require us to incur debt and a lender could not be found to provide that debt, this could have a significant adverse effect on our business, including making it more difficult for us to obtain financing on favorable terms, limiting our ability to capitalize on significant business opportunities, and making us more vulnerable to rising interest rates.

We depend on key personnel and may not be able to retain these employees or recruit additional qualified personnel, which could harm our business.

Our success depends to a significant extent on the continued services of our senior management and other members of management. We have employment agreements with our CEO and division presidents that range from one to three years. If our CEO, our division presidents or other members of senior management do not continue in their present positions, our business may suffer. Because of the specialized scientific nature of our business, we are highly dependent upon attracting and retaining qualified scientific and technical and managerial personnel. While we have a strong record of employee retention, there is still significant competition for qualified personnel in the software, pharmaceutical and biotechnology fields. Therefore, we may not be able to attract and retain the qualified personnel necessary for the development of our business. The loss of the services of existing personnel, as well as the failure to recruit additional key scientific, technical, and managerial personnel in a timely manner, could harm our business.

If we are not successful in selecting and integrating the businesses and technologies we acquire, or in managing our current and future divestitures, our business may suffer.

Over the years, we have expanded our business through acquisitions. We continue to search to acquire businesses and technologies and form strategic alliances. However, businesses and technologies may not be available on terms and conditions we find acceptable. We risk spending time and money investigating and negotiating with potential acquisition or alliance partners, but not completing transactions. Even if completed, acquisitions and alliances involve numerous risks which may include: difficulties in achieving business and continuing financial success; difficulties and expenses incurred in assimilating and integrating operations, services, products, technologies, or pre-existing relationships with our customers, distributors, and suppliers; challenges with developing and operating new businesses, including those which are materially different from our existing businesses and which may require the development or acquisition of new internal capabilities and expertise; challenges of maintaining staffing at the acquired entities, including loss of key employees; potential losses resulting from undiscovered liabilities of acquired companies that are not covered by the indemnification we may obtain from the seller(s); the presence or absence of adequate internal controls and/or significant fraud in the financial systems of acquired companies; diversion of management's attention from other business concerns; acquisitions could be dilutive to earnings, or in the event of acquisitions made through the issuance of our common stock to the shareholders of the acquired company, dilutive to the percentage of ownership of our existing shareholders; new technologies and products may be developed which cause businesses or assets we acquire to become less valuable; and risks that disagreements or disputes with prior owners of an acquired business, technology, service, or product may result in litigation expenses and distribution of our management's attention. In the event that an acquired business or technology or an alliance does not meet our expectations, our results of operations may be adversely affected.

Some of the same risks exist when we decide to sell a business, site, or product line. In addition, divestitures could involve additional risks, including the following: difficulties in the separation of operations, services, products, and personnel; and the need to agree to retain or assume certain current or future liabilities in order to complete the divestiture. We evaluate the performance and strategic fit of our businesses. These and any divestitures may result in significant write-offs, including those related to goodwill and other intangible assets, which could have an adverse effect on our results of operations and financial condition. In addition, we may encounter difficulty in finding buyers or alternative exit strategies at acceptable prices and terms and in a timely manner. We may not be successful in managing these or any other significant risks that we encounter in divesting a business, site, or product line, and as a result, we may not achieve some or all of the expected benefits of the divestitures.

Our quarterly and annual operating results fluctuate and may continue to fluctuate in the future, and if we fail to meet the expectations of analysts or investors, our stock price and the value of your investment could decline substantially.

We believe that operating results for any particular quarter are not necessarily a meaningful indication of future results. Nonetheless, fluctuations in our quarterly operating results could negatively affect the market price of our common stock. Our results of operations in any quarter or annual period have varied in the past and may vary from quarter to quarter or year to year and are influenced by such factors as:

- changes in the general global economy;
- the number and scope of ongoing client engagements; the commencement, postponement, delay, progress, completion, or cancellation of client contracts in the quarter;
- changes in customer budget cycles;
- the number and scope of ongoing client engagements;
- the commencement, postponement, delay, progress, completion, or cancellation of client contracts in the quarter;
- changes in the mix of our products and services;
- competitive pricing pressures;
- the extent of cost overruns;
- buying patterns of our clients;
- budget cycles of our clients;
- the effect of potential acquisitions and consequent integration;
- the timing of new product releases by us or our competitors;
- general economic factors, including factors relating to disruptions in the world credit and equity markets and the related impact on our customers' access to capital;
- changes in tax laws, rules, regulations, and tax rates in the locations in which we operate;
- the timing and charges associated with completed acquisitions and other events;
- the financial performance of the limited partnerships in which we invest; and
- exchange rate fluctuations.

We derive a significant percentage of our revenues from a concentrated group of customers and the loss of more than one of our major customers could materially and adversely affect our business, results of operations or financial condition.

Four customers accounted for 9% (a dealer account in Japan representing various customers), 7%, 6% and 5% of net sales for fiscal year 2018. Three customers accounted for 7% (a dealer account in Japan representing various customers), 7%, and 5% of net sales for fiscal year 2017. Three customers accounted for 10% (a dealer account in Japan representing various customers), 7%, and 6% of net sales for fiscal year 2016. The loss of any of our major customers could have a material adverse effect on our results of operations and financial condition. We may not be able to maintain our customer relationships, and our customers may delay payment under, or fail to renew, their agreements with us, which could adversely affect our business, results of operations, or financial condition. Any reduction in the amount of revenues that we derive from these customers, without an offsetting increase in new sales to other customers, could have a material adverse effect on our operating results. A significant change in the liquidity or financial position of our customers could also have a material adverse effect on the collectability of our accounts receivable, our liquidity, and our future operating results.

A significant portion of our operating expenses is relatively fixed and planned expenditures are based in part on expectations regarding future revenues.

Accordingly, unexpected revenue shortfalls may decrease our gross margins and could cause significant changes in our operating results from year to year. As a result, in future quarters our operating results could fall below the expectations of securities analysts or investors, in which event our stock price would likely decrease.

If our customers cancel their contracts or terminate or delay their clinical trials, we may lose or delay revenues and our business may be harmed.

Certain of our customer contracts are subject to cancellation by our customers at any time with limited notice. Customers engaged in clinical trials may terminate or delay a clinical trial for various reasons, including the failure of the tested product to satisfy safety or efficacy requirements, unexpected or undesired clinical results, decisions to deemphasize a particular product or forgo a particular clinical trial, decisions to downsize clinical development programs, insufficient patient enrollment or investigator recruitment, and production problems resulting in shortages of required clinical supplies. Any termination or delay in the clinical trials would likely result in a consequential delay or termination in those customers' service contracts. We have experienced terminations and delays of our customer service contracts in the past (although no such past terminations have had a significant impact on our results of operations) and we expect to experience additional terminations and delays in the future. The termination of single-study arrangements could result in decreased revenues and the delay of our customers' clinical trials could result in delayed professional services revenues, which could materially harm our business.

If our security is breached, our business could be disrupted, our operating results could be harmed, and customers could be deterred from using our products and services.

Our business relies on the secure electronic transmission, storage, and hosting of sensitive information, including clinical data, financial information, and other sensitive information relating to our customers, company, and workforce. As a result, we face some risk of a deliberate or unintentional incident involving unauthorized access to our computer systems (including, among other methods, cyber- attacks or social engineering) that could result in misappropriation or loss of assets or sensitive information, data corruption, or other disruption of business operations. In light of this risk, we have devoted significant resources to protecting and maintaining the confidentiality of our information, including implementing security and privacy programs and controls, training our workforce, and implementing new technology. We have no guarantee that these programs and controls will be adequate to prevent all possible security threats. We believe that any compromise of our electronic systems, including the unauthorized access, use, or disclosure of sensitive information or a significant disruption of our computing assets and networks, would adversely affect our reputation and our ability to fulfill contractual obligations, and would require us to devote significant financial and other resources to mitigate such problems, and could increase our future cyber security costs.

Moreover, unauthorized access, use, or disclosure of such sensitive information could result in contractual or other liability. In addition, any real or perceived compromise of our security or disclosure of sensitive information may result in lost revenues by deterring customers from using or purchasing our products and services in the future or prompting them to use competing service providers.

Any failure by us to properly protect customer data we possess or are deemed to possess in connection with the conduct of clinical trials, could subject us to significant liability.

Our customers use our solutions to collect, manage, and report information in connection with the conduct of clinical trials. This information may be considered our customers' proprietary information. Since we receive and process our customers' data from customers utilizing our hosted solutions, there is a risk that we could be liable if there were a breach of any obligation to a protected person under contract, standard of practice, or regulatory requirement. If we fail to properly protect our customers' data that is in our possession or deemed to be in our possession, we could be subjected to significant liability and our reputation would be harmed.

We rely upon a single internal hosting facility and Amazon Web Services to deliver our solutions to our customers and any disruption of or interference with our hosting systems, operations, or use of the Amazon Web Services could harm our business and results of operations.

Substantially all of the computer hardware necessary to deliver our CRO and KIWI solutions is located at our internal hosting facility in Buffalo, New York. In addition to our dedicated hosting facility, we utilize third-party cloud computing services from Amazon Web Services ("AWS") to help us efficiently scale our cloud-based solutions and provide training. Because we cannot easily switch our AWS-serviced operations to another cloud provider, any disruption of or interference with our use of AWS would impact our operations, and our business would be adversely impacted. Our systems and operations or those of AWS could suffer damage or interruption from human error, fire, flood, power loss, telecommunications failure, break-ins, terrorist attacks, acts of war, and similar events. The occurrence of a natural disaster, an act of terrorism or other unanticipated problems at our or AWS' hosting facilities could result in lengthy interruptions in our service. Although we and AWS maintain backup facilities and disaster recovery services in the event of a system failure, these may be insufficient or fail. Any system failure, including network, software, or hardware failure, that causes an interruption in our Buffalo data center or our use of AWS or that causes a decrease in responsiveness of our cloud-based solutions could damage our reputation and cause us to lose customers, which could harm our business and results of operations. Our business may be harmed if our customers and potential customers believe our service is unreliable.

Defects or errors in our software applications could harm our reputation, result in significant cost to us and impair our ability to market our solutions.

Our software applications are inherently complex and may contain defects or errors, some of which may be material. Errors may result from our own technology or from the interface of our cloud-based solutions with legacy systems and data, which we did not develop. The risk of errors is particularly significant when a new product is first introduced or when new versions or enhancements of existing products are released. The likelihood of errors is increased when we do more frequent releases of new products and enhancements of existing products. We have, from time to time, found defects in our solutions. Although these past defects have not resulted in any litigation against us to date, we have invested significant capital, technical, managerial, and other resources to investigate and correct these past defects and we have needed to divert these resources from other development efforts. In addition, material performance problems or defects in our solutions may arise in the future. Material defects in our cloud-based solutions could result in a reduction in sales, delay in market acceptance of our solutions, or credits or refunds to our customers. In addition, such defects may lead to the loss of existing customers and difficulty in attracting new customers, diversion of development resources, or harm to our reputation. Correction of defects or errors could prove to be impossible or impractical. The costs incurred in correcting any defects or errors or in responding to resulting claims or liability may be substantial and could adversely affect our operating results.

If we are not able to reliably meet our data storage and management requirements, or if we experience any failure or interruption in the delivery of our services over the Internet, customer satisfaction and our reputation could be

harmed and customer contracts may be terminated.

As part of our current business model, we deliver our software over the Internet and store and manage hundreds of terabytes of data for our customers, resulting in substantial information technology infrastructure and ongoing technological challenges, which we expect to continue to increase over time. If we do not reliably meet these data storage and management requirements, or if we experience any failure or interruption in the delivery of our services over the Internet, customer satisfaction and our reputation could be harmed, leading to reduced revenues and increased expenses. Our hosting services are subject to service-level agreements and, in the event that we fail to meet guaranteed service or performance levels, we could be subject to customer credits or termination of these customer contracts. If the cost of meeting these data storage and management requirements increases, our results of operations could be harmed.

Some of our software solutions and services utilize open source software, and any failure to comply with the terms of one or more of these open source licenses could adversely affect our business.

Some of our software solutions utilize software covered by open source licenses. Open source software is typically freely accessible, usable and modifiable, and is used by our development team in an effort to reduce development costs and speed up the development process. Certain open source software licenses require a user who intends to distribute the open source software as a component of the user's software to disclose publicly part or all of the source code to the user's software. In addition, certain open source software licenses require the user of such software to make any derivative works of the open source code available to others on unfavorable terms or at no cost. This can subject previously proprietary software to open source license terms. While we monitor the use of all open source software in our products, processes and technology and try to ensure that no open source software is used in such a way as to require us to disclose or make available the source code to the related product or solution, such use could inadvertently occur. This could harm our intellectual property position and have a material adverse effect on our business.

We may be unable to adequately enforce or defend our ownership and use of our intellectual property and other proprietary rights.

Our success is heavily dependent upon our intellectual property and other proprietary rights. We rely upon a combination of trademark, trade secret, copyright, patent, and unfair competition laws, as well as license and access agreements and other contractual provisions, to protect our intellectual property and other proprietary rights. In addition, we attempt to protect our intellectual property and proprietary information by requiring certain of our employees and consultants to enter into confidentiality, non-competition, and assignment-of-inventions agreements. The steps we take to protect these rights may not be adequate to prevent misappropriation of our technology by third parties, or may not be adequate under the laws of some foreign countries, which may not protect our intellectual property rights to the same extent as do the laws of the United States. Our attempts to protect our intellectual property may be challenged by others or invalidated through administrative process or litigation, and agreement terms that address non-competition are difficult to enforce in many jurisdictions and may not be enforceable in any particular case. In addition, there remains the possibility that others will "reverse engineer" our products in order to introduce competing products, or that others will develop competing technology independently. If we resort to legal proceedings to enforce our intellectual property rights or to determine the validity and scope of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. The failure to adequately protect our intellectual property and other proprietary rights may have a material adverse effect on our business, results of operations or financial condition.

Current and future litigation against us, which may arise in the ordinary course of our business, could be costly and time consuming to defend.

We are subject to claims that arise in the ordinary course of business, such as claims brought by our customers in connection with commercial disputes and employment claims made by our current or former employees. Third parties may in the future assert intellectual property rights to technologies that are important to our business and demand back royalties or demand that we license their technology. Litigation may result in substantial costs and may divert management's attention and resources, which may seriously harm our business, overall financial condition, and operating results. Insurance may not cover such claims, may not be sufficient for one or more such claims, and may not continue to be available on terms acceptable to us. A claim brought against us that is uninsured or underinsured could result in unanticipated costs, negatively affecting our business, results of operations, and financial condition.

We could incur substantial costs resulting from product liability claims relating to our products or services or our customers' use of our products or services.

Any failure or errors in a customer's clinical trial caused or allegedly caused by our products or services could result in a claim for substantial damages against us by our customers or the clinical trial participants, regardless of our

responsibility for the failure. Although we are generally entitled to indemnification under our customer contracts against claims brought against us by third parties arising out of our customers' use of our products, we might find ourselves entangled in lawsuits against us that, even if unsuccessful, may divert our resources and energy and adversely affect our business. Further, in the event we seek indemnification from a customer, a court may not enforce our indemnification right if the customer challenges it or the customer may not be able to fund any amounts for indemnification owed to us. In addition, our existing insurance coverage may not continue to be available on reasonable terms or may not be available in amounts sufficient to cover one or more large claims, or the insurer may disclaim coverage as to any future claim.

Our Buffalo Subsidiary (Cognigen) depends on the clinical trial market, and a downturn in this market could cause our revenues to decrease.

Our Buffalo business depends entirely on the clinical trials conducted or sponsored by pharmaceutical, biotechnology and medical device companies, CROs, and other entities. Our revenues may decline as a result of conditions affecting these industries, including general economic downturns, increased consolidation, decreased competition, or fewer products under development. Other developments that may affect these industries and harm our operating results include product liability claims, changes in government regulation, changes in governmental price controls or third-party reimbursement practices, and changes in medical practices. Disruptions in the world credit and equity markets may also result in a global downturn in spending on research and development and clinical trials and may impact our customers' access to capital and their ability to pay for our solutions. Any decrease in research and development expenditures or in the size, scope, or frequency of clinical trials could materially adversely affect our business, results of operations, or financial condition.

As a public company, we may incur significant administrative workload and expenses in connection with new and changing compliance requirements.

As a public company with common stock listed on The Nasdq Capital Market, we must comply with various laws, regulations and requirements. New laws and regulations, as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and rules adopted by the SEC and by The Nasdaq Capital Market, may result in increased general and administrative expenses and a diversion of management's time and attention as we respond to new requirements.

We have been paying quarterly dividends on our common stock, and although there has been a consistent track record of paying these dividends, the Board of Directors may suspend the dividend, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

Should the Board of Directors suspend the dividend and decide to use those funds to invest more into the business, you may not receive any dividends on your investment in our common stock for the foreseeable future and the success of an investment in shares of our common stock will depend upon any future appreciation in its value. Shares of our common stock may depreciate in value or may not appreciate in value.

Risks Related to Our Common Stock - The price of our common stock may fluctuate significantly and investors could lose all or part of their investments.

Shares of our common stock were sold in our initial public offering ("IPO") in 1996 at a price of $1.25 per share (on a post-split basis), and our common stock has subsequently traded as high as $23.95 and as low as $0.38 from our IPO through August 31, 2018. However, an active, liquid, and orderly market for our common stock on The Nasdaq Capital Market or otherwise may not be sustained, which could depress the trading price of our common stock. The trading price of our common stock may be subject to wide fluctuations in response to various factors, some of which are beyond our control, including:

- our quarterly or annual earnings or those of other companies in our industry;
- announcements by us or our competitors of significant contracts or acquisitions;
- changes in accounting standards, policies, guidance, interpretations, or principles;
- general economic and stock market conditions, including disruptions in the world credit and equity markets;
- the failure of securities analysts to cover our common stock or changes in financial estimates by analysts;
- future sales of our common stock; and

· the other factors described in these "Risk Factors."

In recent years, the stock market in general, and the market for technology-related companies in particular, has experienced wide price and volume fluctuations. This volatility has had a significant impact on the market price of securities issued by many companies, including companies in our industry. The price of our common stock could fluctuate based upon factors that have little to do with our performance, and these fluctuations could materially reduce our stock price.

In the past, some companies, including companies in our industry, have had volatile market prices for their securities and have had securities class action suits filed against them. The filing of a lawsuit against us, regardless of the outcome, could have a material adverse effect on our business, financial condition, and results of operations, as it could result in substantial legal costs and a diversion of our management's attention and resources.

ITEM 1B – UNRESOLVED STAFF COMMENTS

None.

ITEM 2 –PROPERTIES

We lease approximately 13,500 square feet of office space in Lancaster, California. The original lease had a five-year term with two, three-year options to extend. The initial five-year term expired in February 2011, and we extended the lease to February 2, 2014. In June 2013, the lease was amended to extend the term to February 2, 2017. The amended lease also provides for an annual base rent increase of 3% per year and two, two-year options to extend. In May 2016 the Company exercised the two, two-year options extending the term of the lease through February 2, 2021 at a fixed rate of $25,000 per month. The new extension agreement gives the Company the right, upon 90 days' prior notice, to terminate the lease in the last two years of the term upon payment of a recapture payment equal to the 3% base payment increase that would have been due under the original agreement.

Our Buffalo subsidiary leases approximately 12,623 square feet of space in Buffalo, New York. The initial five-year term expired in October 2018 and was renewed for a three-year option to extending it to October 2021. The new base rent is $16,147 per month.

In September 2017 DILIsym Services, Inc. signed a 3-year lease for approximately 1,900 rentable square feet of space in Research Triangle Park, North Carolina. The initial three-year term expires in October 2020. The base rent is $3,975 per month with an annual 3% adjustment. Prior to this lease DILIsym was on a month-to-month rental.

Rent expense, including common area maintenance fees for the fiscal years ended August 31, 2018, 2017 and 2016 was $567,000, $509,600, and $491,800, respectively.

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

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

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, par value $0.001 per share, trades on the Nasdaq Capital Market under the symbol "SLP."

Price Range of Common Stock

The following table shows high and low sales prices for the Company's common stock for each quarter during the past two fiscal years:

	High	Low
FY17:		
Quarter ended November 30, 2016	$10.75	$8.10
Quarter ended February 28, 2017	$10.50	$8.81
Quarter ended May 31, 2017	$12.75	$9.70
Quarter ended August 31, 2017	$16.15	$11.50
FY18:		
Quarter ended November 30, 2017	$17.45	$14.25
Quarter ended February 28, 2018	$17.05	$15.16
Quarter ended May 31, 2018	$19.95	$14.25
Quarter ended August 31, 2018	$23.95	$16.70

Holders

As of November 14, 2018, there were 40 shareholders of record.

Dividends

We paid a total of approximately $4.2 million in cash dividends during fiscal years 2018, and $3.4 million in fiscal year 2017 as set forth in the table below. We expect to pay quarterly dividends of $0.06 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
2017	11/10/2016	11/17/2016	17,226,478	$ 0.05	$861,324
	1/30/2017	2/6/2017	17,233,758	$ 0.05	$861,688
	5/08/2017	5/15/2017	17,240,626	$ 0.05	$862,031
	7/28/2017	8/4/2017	17,268,920	$ 0.05	$863,446
2018	11/13/2017	11/20/2017	17,284,792	$ 0.06	$1,037,088
	1/26/2018	2/2/2018	17,317,752	$ 0.06	$1,039,065
	4/25/2018	5/02/2018	17,354,005	$ 0.06	$1,041,240
	7/26/2018	8/2/2018	17,405,775	$ 0.06	$1,044,347

Shareholder Return Performance Presentation

The following graph compares the cumulative total stockholder return on our common stock of a $100 investment from August 31, 2013 through August 31, 2018 assuming reinvestment of dividends, with a similar investment in the Russell 3000 index (the "Russell 3000") and with the companies listed in the Nasdaq Composite - Total Returns ("IXIC"), and the S&P600 Health Care Equipment & Services Industry Group Index (SP600-3510). The historical information set forth below is not necessarily indicative of future performance. This performance graph shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended or incorporated by reference into any of our filings under the Securities Act of 1933, as amended, of the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Equity Compensation Plan Information

The following information is provided as of August 31, 2018:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,134,976	$ 9.44	923,765
Equity compensation plans not approved by security holders	-0-	-0-	-0-
Total	1,134,976	$ 9.44	923,765

Repurchases

There is currently no share repurchase program pending, and the Company has made no repurchases of its securities since fiscal year 2011.

ITEM 6 – SELECTED FINANCIAL DATA

The following tables set forth the selected consolidated financial data for each of the fiscal years in the five-year period ended August 31, 2018. We derived the selected consolidated financial data from our audited consolidated financial statements, which should be read in conjunction with Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations in Part II of this Annual Report on Form 10-K and our consolidated financial statements and the related notes included elsewhere in this report.

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	Year ended August 31,				
Statements of operations data	**2018[d]**	**2017[a]**	**2016**	**2015[b]***	**2014[c]***
Net Revenues	$29,666,524	$24,137,913	$19,972,079	$18,314,248	$11,460,880
Cost of revenues	7,994,228	6,307,800	4,601,513	4,392,477	1,628,069
Gross margin	21,672,296	17,830,113	15,370,566	13,921,771	9,832,811
SG&A expenses	9,583,852	8,198,184	6,693,691	6,736,767	4,439,665
R&D	1,790,656	1,367,645	1,445,069	1,328,476	952,774
Total operating expenses	11,374,508	9,565,829	8,138,760	8,065,243	5,392,439
Income from operations	10,297,788	8,264,284	7,231,806	5,856,528	4,440,372
Other income (expense)	(158,846)	(24,017)	4,586	(163,599)	73,925
Income from operations before income taxes	10,138,942	8,240,267	7,236,392	5,692,929	4,514,297
Provision for income taxes	(1,204,130)	(2,452,670)	(2,286,256)	(1,849,968)	(1,487,806)
Net Income	$8,934,812	$5,787,597	$4,950,136	$3,842,961	$3,026,491
Earnings per share					
Basic	$0.52	$0.34	$0.29	$0.23	$0.19
Diluted	$0.50	$0.33	$0.29	$0.23	$0.18
Weighted-average common shares outstanding					
Basic	17,328,707	17,239,490	17,028,566	16,864,670	16,173,674
Diluted	17,860,392	17,515,917	17,209,506	17,032,158	16,407,751
Dividend per common share	$.24	$0.20	$0.20	$0.20	$0.19
Dividends	$4,161,740	$3,448,489	$3,413,274	$3,375,566	$3,075,585

	As of August 31, 2018				
Balance sheet data at year end	2018	2017	2016	2015*	2014*
Cash and cash equivalents	9,400,701	6,215,718	8,030,284	8,551,275	8,614,929
Net working capital	12,996,901	10,625,437	10,574,712	7,708,494	10,027,035
Total assets	43,279,016	38,512,468	27,814,317	27,133,254	20,865,998
Total liabilities associated with business and intangible acquisitions	5,890,940	5,985,516	1,000,000	3,604,404	2,500,000
Total liabilities	11,356,391	12,707,581	5,081,723	7,601,052	5,430,647
Total shareholders' equity	31,922,625	25,804,887	22,732,594	19,532,202	15,435,351

*Amount reclassified for presentation used in 2018

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Notes to Five-Year Summary

[a] Effective June 1, 2017, we acquired DILIsym Services, Inc. and incurred approximately $620,000 of acquisition related costs in FY2017.

[b] Effective September 2, 2014 we acquired Cognigen Corporation and incurred approximately $308,000 of acquisition related costs in FY 2014 and $410,000 in FY 2015.

[c] In May 2014, the Company entered into an exclusive software licensing agreement with TSRL, Inc. (aka Therapeutic Systems Research Laboratories), pursuant to which TSRL licensed certain software technology and databases to us, and we paid royalties to TSRL. 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. All payments were made as of April 2017. The $6,000,000 is being amortized at a constant rate of $600,000 per year until it is completely amortized, after which no further expense will be incurred.

[d] In FY2018 the Company posted a $1.5 million deferred tax benefit due to the effect of new tax rates enacted under the Tax Cuts and Jobs Act of 2017.

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 2018 highlights:

- We released ADMET Predictor versions 8.5 and 9.0
- We released GastroPlus version 9.6
- We released PKPlus version 2.0
- We released DILIsym® version 7A
- Entered into a one-year funded research collaboration with a large European consortium to further develop and validate the mechanistic Transdermal Compartmental Absorption and Transit (TCAT™) model in GastroPlus™
- Simulations Plus subsidiary DILIsym was awarded a Fast-Track SBIR grant to fund the development of software for predicting drug-induced kidney injury
- We released Version 2 of its KIWI™ Pharmacometric Communication and Collaboration Platform
- We successfully hired a new CEO with our founding CEO remaining as Chairman of the Board
- Continued quarterly payment of dividend raising it to 6 cents per share on a quarterly basis

Fiscal Year 2018 Financial Summary:

- Consolidated net revenues increased by $5.53 million, or 22.9%, to $29.7 million in fiscal year 2018 from $24.1 million in fiscal year 2017.
- Consolidated gross margin increased $3.84 million or 16.0%, to $21.7 million in fiscal year 2018 from $17.8 million in fiscal year 2017.
- Net income from operations increased $2.03 million, or 24.6%, to $10.3 million in fiscal year 2018 from $8.3 million in fiscal year 2017.
- Net income increased by $3.15 million, or 54.4%, to $8.9 million in fiscal year 2018 from $5.8 million in fiscal year 2017.
- Diluted earnings share increased by $0.17 or 51.4% to $0.50 in 2018 from $0.33 from 2017.

Strategy Going Forward:

- Continue to pursue funded and unfunded collaborations in support of improving our products and services
- Continue to seek accretive acquisitions that complement our existing offerings and expand our markets
- Continue our aggressive marketing and sales campaign, including numerous scientific conferences and meetings
- Continue to expand our use of social media and advertising
- Continue to expand our sales staff, both in-house and in the field
- Continue to recruit scientific and other resources to support our product and scientific consulting services.
- Expand our publishing activities in scientific journals

Fiscal year 2018 was yet another record year. We believe the continued growth of our pharmaceutical software and services business is the result of steadily increasing adoption of simulation and modeling software tools across the pharmaceutical industry, the push by regulatory agencies for increased use of modeling and simulation, and 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., Europe, and Japan.

Our financial performance has enabled us to maintain significant cash deposits, continue our research and development activities, and invest in staffing to meet the needs of a wider customer base, as well as to distribute significant cash dividends to our shareholders.

We do not have any stock repurchase programs currently in place or pending; however, our Board of Directors may consider additional programs from time to time.

Results of Operations

FY18 COMPARED WITH FY17

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, 2018 (FY18) and August 31, 2017 (FY17) (because of rounding, numbers may not foot).

	Fiscal year ended			
	8/31/18		**8/31/17**	
Net revenues	$29,667	100.00%	$24,138	100.0%
Cost of revenues	7,994	26.9	6,308	26.1
Gross margin	21,672	73.1	17,830	73.9
Selling, general and administrative	9,584	32.3	8,198	34.0
Research and development	1,791	6.0	1,368	5.6
Total operating expenses	11,375	38.3	9,566	39.6
Income from operations	10,298	34.7	8,264	34.2
Other income (Exp)	(159)	(0.5))	(24)	(0.1)
Net income before taxes	10,139	34.2	8,240	34.1
(Provision) for income taxes	(1,204)	(4.1))	(2,453)	(10.1)
Net income	$8, 935	30.1%	$5,788	24.0%

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Net Revenues

Consolidated net revenues increased by 22.9% or $5.53 million to $29.67 million in FY18 from $24.14 million in FY17. Our Lancaster, California division increased $1.95 million or 12.5%, to $17.6 million in FY18 from $15.6 million in FY17. $557,000 of this increase was from revenues generated by our Buffalo subsidiary (Cognigen), an increase of 7.6%. DILIsym Services, Inc. (DILIsym), recorded revenues of $4.3 million; in FY17 revenues were $1.2 million for the period of June 1, 2017 thru the end of fiscal year August 31, 2017. FY18 software license sales increased $1.03 million while consulting revenues increased by $4.49 million compared to FY17; $3.2 million of the consulting increase was revenues of DILIsym Services Inc.

Cost of Revenues

Consolidated cost of revenues increased by $1.69 million or 26.7% to $8.0 million in FY18 from $6.31 million in FY17. Labor-related cost accounted for $922,000 of this increase, a combination of increased labor count, salary increases, and bonuses at our subsidiaries based on increased earnings. Included in the increase was $505,000 of salary expense at DILIsym. Other significant increases in cost of revenues included $393,000 of increase direct contract expenses paid for testing at DILIsym. We saw a decrease of approximately $65,000 in training related expenses in FY2018.

A significant portion of cost of revenues for pharmaceutical software products is the systematic amortization of capitalized software development costs, which is an independent fixed cost rather than a variable cost related to revenues. This amortization cost increased approximately $203,000 in FY18 compared with FY17. In addition, in 2018 there was an additional $238,000 of amortization expense associated with acquired technologies associated with DILIsym’s drug-induced liver injury technologies.

Cost of revenues as a percentage of revenue increased to 26.9% in FY18 from 26.1% in FY17. The majority of this percentage change is a result of the increased salary costs associated with consulting costs and the blend of software sales compared to consulting services during FY18.

Gross Margin

Consolidated gross margin increased $3.84 million or 21.5%, to $21.67 million in FY18 from $17.83 million in FY17. $1.5 million of this increase is from the California division, which showed an 82.6% gross margin. The Buffalo Division Gross margins increased $437,000 or 10.4% with margins of 58.9%. DILIsym of North Carolina showed $2.54 million, a 59.6% margin vs a 55.2% margin in FY17 which represented only one quarters worth of activities.

Overall gross margin decreased to 73.1% in FY18 from 73.9% in FY17 due to increased salary costs associated with the relatively higher revenue mix of consulting to software in FY17.

Selling, General and Administrative Expenses

Selling, general, and administrative (SG&A) expenses increased $1.39 million, or 16.9% to $9.58 million in FY18 from $8.19 million in FY17. As a percent of revenues, SG&A was 32.31% for FY18, compared to 33.96% in FY17 and 33.52% in FY16.

The major increases in SG&A expense were:

- Commission expenses were up $175,000, mainly related to increased sales through representatives in Asia
- Accounting and audit fees increased by $40,000 associated with costs of consolidated audits and other compliance-related expenses
- Contract labor increased $187,000 mainly due to increase director fees
- G&A Salaries and Wages increased by $621,000; this increase is a combination of increased salaries of $255,000 at DILIsym, annual salary increases and increased in head count.
- Insurance Expense increased $247,000; $234,000 was health-related medical costs of which $98,000 was associated with DILIsym.
- Payroll tax expense increased $204,000, the effect of higher salary expense of which $98,000 was DILIsym
- 401k expense increased $75,000 due to the increased staffing and full year of employees at DILIsym
- Trade shows, and travel expense increased $125,000
- Rent increase $57,000 due mainly to the addition of DILIsym in June 2017
- Amortization expense increased $158,000 due to increase acquisition amortization for DILIsym intangibles

The major decreases in SG&A expense were:

- G&A expenses categories for consulting, legal, and accounting decrease by a total of $620,000 in FY18 as in FY17 there were one-time charges associated with the acquisition of DILIsym Services.

Research and Development

We incurred approximately $3,936,000 of research and development costs during FY18. Of this amount, $2,145,000 was capitalized and $1,791,000 was expensed. We incurred approximately $2,743,000 of research and development costs during FY17. Of this amount, $1,376,000 was capitalized and $1,367,000 was expensed. The increase of $1.193,000, or 43.5%, in total research and development expenditures from FY17 to FY18 was mainly from $504,000 of costs incurred by DILIsym Services Inc.

Provision for Income Taxes

The provision for income taxes was $1.20 million for FY18 compared to $2.45 million for FY17. Our effective tax rate decreased to 11.9% in FY18 from 29.8% in FY17. This decrease is a results mainly from a second quarter 2018 assessment of deferred taxes based on the new tax rates enacted under the Tax Cuts and Jobs Act of 2017 (the “2017 Tax Act). Financial Accounting Standards Board (“FASB”) Accounting Standards Codification Topic 740, Income Taxes (“ASC 740”) requires that the company recognize the effects of changes in tax laws or tax rates in the financial statements for the period in which such changes were enacted. Among other things, changes in tax laws or tax rates can affect the amount of taxes payable for the current period, as well as the amount and timing of deferred tax liabilities and deferred tax assets. Based on the assessment the Company posted a one time tax benefit in the amount of $1,500,000 in the second fiscal quarter of 2018, the result of estimating future deferred liabilities at the lower tax rates under the newly enacted tax laws.

Net Income

Net income increased by $3.15 million or 54.4%, to $8.93 million in FY18 from $5.79 million in FY17. Of note, this increase includes a one-time deferred tax benefit of $1.5 million as discuss above in the note on Provision for Income Taxes, and the a full years net income for DILIsym Services, Inc.

FY17 COMPARED WITH FY16

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, 2017 (FY17) and August 31, 2016 (FY16) (because of rounding, numbers may not foot).

	Fiscal years ended			
	8/31/17		**8/31/16**	
Net revenues	$24,138	100.0%	$19,972	100.0%
Cost of revenues	6,308	26.1	4,602	23.0
Gross margin	17,830	73.9	15,370	77.0
Selling, general and administrative	8,198	34.0	6,694	33.5
Research and development	1,368	5.6	1,445	7.3
Total operating expenses	9,566	39.6	8,139	40.8
Income from operations	8,264	34.2	7,232	36.2
Other income	(24)	(0.1)	4	(0.0)
Net income before taxes	8,240	34.1	7,236	36.2
(Provision) for income taxes	(2,253)	(10.1)	(2,286)	(11.4)
Net income	$5,788	24.0%	$4,950	24.8%

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Net Revenues

Consolidated net revenues increased by 20.9% or $4.17 million to $24.14 million in FY17 from $19.97 million in FY16. $1.75 million of this increase was from revenues generated by our Buffalo subsidiary (Cognigen), an increase of 31.4%. Our Lancaster, California division increased $1.18 million or 8.2%, to $15.6 million in FY17 from $14.42 million in FY16. DILIsym Services, Inc. (DILIsym), our June 1st 2017 acquisition located in North Carolina, recorded revenues of $1.24 million. FY17 software license sales increased $1.07 million while consulting revenues increased by $3.1 million compared to FY16.

Cost of Revenues

Consolidated cost of revenues increased by $1.71 million or 37.1% to $6.31 million in FY17 from $4.60 million in FY16. Labor-related cost accounted for $1.02 million of this increase, a combination of increased labor count, salary increases, and bonuses at our subsidiaries based on increased earnings. Included in the increase was $115,000 of salary expense at DILIsym. Other significant increases in cost of revenues included $314,000 of direct contract expenses paid for testing at DILIsym, and approximately $119,000 of increased training related expenses.

A significant portion of cost of revenues for pharmaceutical software products is the systematic amortization of capitalized software development costs, which is an independent fixed cost rather than a variable cost related to revenues. This amortization cost increased approximately $116,000 in FY17 compared with FY16. In addition, in 2017 there was an additional $86,000 of amortization expense associated with acquired technologies associated with DILIsym's drug-induced liver injury technologies.

Cost of revenues as a percentage of revenue increased to 26.1% in FY17 from 23.0% in FY16. The majority of this percentage change is a result of the increased salary costs associated with consulting costs and the blend of software sales compared to consulting services during FY17.

Gross Margin

Consolidated gross margin increased $2.46 million or 16.0%, to $17.83 million in FY17 from $15.37 million in FY16. $805,000 of this increase is from the California division, which showed an 83.0% gross margin. The Buffalo Division Gross margins increased $972,000 or 30.2% with margins of 58%, and DILIsym of North Carolina showed $683,000, a 55.2% margin.

Overall gross margin decreased to 73.9% in FY17 from 76.9% in FY16 due to increased salary costs associated with the relatively higher revenue mix of consulting to software in FY17.

Selling, General and Administrative Expenses

Selling, general, and administrative (SG&A) expenses increased $1.50 million, or 22.5% to $8.19 million in FY17 from $6.69 million in FY16.

The major increases in SG&A expense were:

- In 2017 the Company incurred approximately $620,000 of one-time charges associated with the acquisition of DILIsym Services, Inc.; these included legal, accounting, and investment banking fees
- Commission expenses were up $62,000, related to increased sales through representatives in Asia
- Accounting and audit fees increased by $127,000 associated with costs of consolidated audits and other compliance-related expenses for the first year of accelerated filer status
- G&A Salaries and Wages increased by $400,000; this increase is a combination of increased stock compensation costs of $70,000, salaries of $62,000 at DILIsym during the last fiscal quarter after acquisition, annual salary increases and increased head count in Lancaster and Buffalo.
- Insurance Expense increased $95,000; $86,000 was health-related medical costs of which $33,000 was associated with DILIsym.
- Payroll tax expense increased $80,000, the effect of higher salary expense of which $22,000 was DILIsym
- Legal expenses increased $61,000 due to document review and review of other strategic initiatives
- Amortization expense increased $53,000 due to new acquisition amortization for DILIsym intangibles

The major decreases in SG&A expense were:

- Advertising expenses decreased by $73,000; in 2016 the Company incurred greater advertising expense to upgrade its website

Research and Development

We incurred approximately $2,743,000 of research and development costs during FY17. Of this amount, $1,376,000 was capitalized and $1,367,000 was expensed. We incurred approximately $2,641,000 of research and development costs during FY16. Of this amount, $1,196,000 was capitalized and $1,445,000 was expensed. The increase of $104,000, or 4%, in total research and development expenditures from FY16 to FY17 was mainly from $71,000 of costs incurred by DILIsym Services Inc.

Provision for Income Taxes

The provision for income taxes was $2.45 million for FY17 compared to $2.29 million for FY16. Our effective tax rate decreased to 29.8% in FY17 from 31.6% in FY16. This decrease is a result of additional tax deductions for stock-based compensation.

Net Income

Net income increased by $837,000 or 16.9%, to $5.79 million in FY17 from $4.95 million in FY16. Of note, this increase is in spite of the fact that during FY17 stock compensation costs increased by $238,000 and $620,000 of one-time pretax costs were incurred associated with the acquisition of DILIsym services.

SEASONALITY

Our sales exhibit some seasonal fluctuations, with the fourth fiscal quarter (June-August) generally having the lowest sales over the past three fiscal years because of summer vacations and reduced activities at our customers' sites. In 2017, revenues in the fourth quarter revenues were higher increased due to the acquisition of DILIsym along with increased revenues at our Buffalo Division. This unaudited quarterly sales information has been prepared on the same basis as the annual information presented elsewhere in this Annual Report on Form 10-K and, in the opinion of management, reflects all adjustments (consisting of normal recurring entries) necessary for a fair presentation of the information presented. Net sales for any quarter are not necessarily indicative of sales for any future period; however, because our pharmaceutical software is licensed on an annual basis, renewals are usually within the same quarter year after year. (Numbers may not foot because of rounding)

Net Sales (in thousands of dollars)

FY	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
2018	$ 7,069	7,357	8,553	6,688	$29,667
2017	$ 5,418	5,706	6,748	6,265	$24,138
2016	$ 4,839	5,164	6,011	3,958	$19,972
2015	$ 4,086	4,574	5,942	3,712	$18,314
2014	$ 2,641	3,081	3,741	1,998	$11,461
2013	$ 2,290	3,118	3,095	1,568	$10,071
2012	$ 2,248	2,789	2,772	1,640	$9,449
2011	$ 2,050	2,622	2,640	1,427	$8,739
2010	$ 1,735	2,227	2,325	1,334	$7,621

LIQUIDITY AND CAPITAL RESOURCES

Our principal source of capital has been cash flow from our operations. We have achieved continuous positive operating cash flow over the last twelve fiscal years. We believe that our existing capital and anticipated funds from operations will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for the foreseeable future. Thereafter, if cash generated from operations is insufficient to satisfy our capital requirements, we may open a revolving line of credit with a bank, or we may have to sell additional equity or debt securities or obtain credit facilities. In the event such financing is needed in the future, there can be no assurance that such financing will be available to us, or, if available, that it will be in amounts and on terms acceptable to us.

We are not aware of any trends or demands, commitments, events or uncertainties that are reasonably likely to result in a decrease in liquidity of our assets. The trend over the last ten years has been increasing cash deposits from our operating cash flows, and we expect that trend to continue for the foreseeable future. In FY14 we used $2,500,000 of our cash reserves to pay the initial installment of the amounts we owe under termination and non-assertion agreement we entered into with TSRL in May 2014 that terminated the exclusive software licensing agreement we entered with TSRL in 1997. We also incurred $2,500,000 of debt in connection with termination and non-assertion agreement. We have been paying that debt out of, and anticipate that that debt will continue to be, paid out of operations from the reduction in royalty payments that are no longer payable under the 1997 licensing agreement as a result of its termination.

On July 23, 2014, we signed the Merger Agreement with Cognigen. The merger closed on September 2, 2014, subsequent to the end of FY14, and Cognigen became our wholly-owned subsidiary. In connection with the closing we paid $2,080,000 in cash and issued 491,159 shares of common stock of the Company to the former Cognigen stockholders. The 491,159 shares were valued at $3,120,000 based on a $6.35 per share price, which was the volume-weighted average closing price of our common stock for the 30 consecutive trading-day period ending two trading days before the closing date. In July 2016, we paid the additional $720,000 in cash due, and issued the additional 170,014 shares of common stock due, to the former Cognigen stockholders, which additional shares were valued at $1,080,000 under the formula described above.

On May 1, 2017 we signed a stock acquisition agreement with DILIsym Services, Inc. of Research Triangle Circle, North Carolina, and on June 1, 2017 consummated the acquisition of all the outstanding capital stock of DILIsym Services, Inc. pursuant to a Stock Purchase Agreement. DILIsym became a wholly-owned subsidiary of Simulations Plus. Under the terms of the Agreement, the Company: (1) paid to the DILIsym Shareholders Five Million Dollars, $4,515,982 payable at the closing of the Acquisition subject to certain adjustments and holdbacks and will pay to the DILIsym Shareholders certain earn-out payments, to be measured by the earnings of DILIsym before income taxes, payable following the Closing, as more particularly described in the Agreement and as more fully described in Note 13.

We will continue to seek opportunities for strategic acquisitions. If one or more such acquisitions is identified, a substantial portion of our cash reserves may be required to complete it; however, we intend to maintain sufficient cash reserves after any acquisition to provide reasonable assurance that outside financing will not be necessary to continue operations. If we identify an attractive acquisition that would require more cash to complete than we are willing or able to use from our cash reserves, we will consider financing options to complete the acquisition, including obtaining loans and issuing additional securities.

Quarterly dividend payments made in FY17 and FY18 are listed in the following table.

Fiscal Year	Record Date	Distribution Date	# of Shares Outstanding on Record Date	Dividend per Share	Total Amount
2017	11/10/2016	11/17/2016	17,226,478	$ 0.05	$861,324
	1/30/2017	2/6/2017	17,233,758	$ 0.05	$861,688
	5/08/2017	5/15/2017	17,240,626	$ 0.05	$862,031
	7/28/2017	8/4/2017	17,268,920	$ 0.05	$863,446
2018	11/13/2017	11/20/2017	17,284,792	$ 0.06	$1,037,088
	1/26/2018	2/2/2018	17,317,752	$ 0.06	$1,039,065
	4/25/2018	5/02/2018	17,354,005	$ 0.06	$1,041,240
	7/26/2018	8/2/2018	17,405,775	$ 0.06	$1,044,347

The Board of directors has indicated its intension to pay $0.06 quarterly dividends; however, there can be no assurances that our Board of Directors will continue the dividend distributions as the decision is made on a quarterly basis based on current financial conditions and strategic plans. In November 2018, our Board of Directors declared and paid a dividend distribution of $0.06 per share.

KNOWN TRENDS OR UNCERTAINTIES

Although we have not seen any significant reduction in revenues to date, we have seen some consolidation in the pharmaceutical industry during economic downturns. These consolidations have not had a negative effect on our total sales to that industry; however, should consolidations and downsizing in the industry continue to occur, those events could adversely impact our revenues and earnings going forward.

We believe that the need for improved productivity in the research and development activities directed toward developing new medicines will continue to result in increasing adoption of simulation and modeling tools such as those we produce. New product developments in the pharmaceutical business segments could result in increased revenues and earnings if they are accepted by our markets; however, there can be no assurances that new products will result in significant improvements to revenues or earnings. For competitive reasons, we do not disclose all of our new product development activities.

Our continued quest for acquisitions could result in a significant change to revenues and earnings if one or more such acquisitions are completed.

The potential for growth in new markets (e.g., aerospace and healthcare) is uncertain. We will continue to explore these opportunities until such time as we either generate sales or determine that resources would be more efficiently used elsewhere.

INFLATION

We have not been affected materially by inflation during the periods presented, and no material effect is expected in the near future.

OFF-BALANCE SHEET ARRANGEMENTS

As of August 31, 2018, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not materially exposed to any financing, liquidity, market, or credit risk that could arise if we had engaged in such relationships.

We do not have relationships or transactions with persons or entities that derive benefits from their non-independent relationship with us or our related parties.

CONTRACTUAL OBLIGATIONS

The following table provides aggregate information regarding our contractual obligations as of August 31, 2018. (in thousands)

	Payments due by period				
Contractual obligations:	Total	Less than 1 year	1–3 years	3–5 years	More than 5 years
Operating lease obligations	$1,465	$ 554	$911	$ –	$ –
Contracts Payable	5,890	2,556	3,334	–	–
Total	$7,355	$ 3,110	$4,245	$ –	$ –

RECENTLY ISSUED OR NEWLY ADOPTED ACCOUNTING STANDARDS

In May 2014, the Franchise Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09). The standard will eliminate the transaction- and industry-specific revenue recognition guidance under current generally accepted accounting principles in the U.S. (GAAP) and replace it with a principles-based approach for determining revenue recognition. ASU 2014-09 is effective for annual and interim periods beginning after December 15, 2017. Early adoption is permitted for years beginning after December 15, 2016. The revenue recognition standard is required to be applied retrospectively, including any combination of practical expedients as allowed in the standard. We are evaluating the impact, if any, of the adoption of ASU 2014-09 to our financial statements and related disclosures. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

In November 2015, the FASB issued ASU No 2015-17, *Income Taxes (Topic 740)* (“ASU 2015-17). The amendments in ASU 2015-17 change the requirements for the classification of deferred taxes on the balance sheet. Currently, GAAP requires an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. To simplify the presentation of deferred income taxes, the amendments in this ASU require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The pronouncement is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2016. Earlier application is permitted for all entities as of the beginning of an interim or annual reporting period. The Company has early adopted this pronouncement for the fiscal reporting period ended August 31, 2017 because it reduced complexity while maintaining the usefulness of the information. The retrospective application resulted in a reclassification of the current deferred tax asset at August 31, 2016 now being presented against the long term deferred tax liability.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which supersedes existing guidance on accounting for leases in "Leases (Topic 840)" and generally requires all leases to be recognized in the consolidated balance sheet. ASU 2016-02 is effective for annual and interim reporting periods beginning after December 15, 2018; early adoption is permitted. The provisions of ASU 2016-02 are to be applied using a modified retrospective approach. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting* (ASU 2016-09). This ASU affects entities that issue share-based payment awards to their employees. The ASU is designed to simplify several aspects of accounting for share-based payment award transactions which include - the income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and forfeiture rate calculations. ASU 2016-09 will become effective for the Company in the first quarter of fiscal 2019. Early adoption is permitted in any interim or annual period. The Company early adopted ASU No. 2016-09. The adoption had no material impact on the Company’s financial statements.

In April 2016, the FASB issued AS 2016-10, Revenue from Contracts with Customers (Topic 606), which amends certain aspects of the Board's new revenue standard, ASU 2014-09, Revenue from Contracts with Customers. The standard should be adopted concurrently with adoption of ASU 2014-09 which is effective for annual and interim periods beginning after December 15, 2017. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

SIGNIFICANT ACCOUNTING POLICIES

Estimates

Our financial statements and accompanying notes are prepared in accordance with GAAP. Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses. These estimates and assumptions are affected by management's application of accounting policies. Actual results could differ from those estimates. Significant accounting policies for us include revenue recognition, accounting for capitalized software development costs, valuation of stock options, and accounting for income taxes.

Revenue Recognition

We recognize revenues related to software licenses and software maintenance in accordance with the FASB Accounting Standards Codification ("ASC") 985-605, "Software – Revenue Recognition". Software product revenue is recorded when the following conditions are met: 1) evidence of arrangement exists; 2) delivery has been made; 3) the amount is fixed; and 4) collectability is probable. Post-contract customer support ("PCS") obligations are insignificant; therefore, revenue for PCS is recognized at the same time as the licensing fee, and the costs of providing such support services are accrued and amortized over the obligation period.

As a byproduct of ongoing improvements and upgrades for the new programs and new modules of software, some modifications are provided to our customers who have already purchased software at no additional charge. Other software modifications result in new, additional cost modules that expand the functionality of the software. These are licensed separately. We consider the modifications that are provided without charge to be minimal, as they do not significantly change the basic functionality or utility of the software, but rather add convenience, such as being able to plot some additional variable on a graph in addition to the numerous variables that had been available before, or adding some additional calculations to supplement the information provided from running the software. Such software modifications for any single product have typically occurred once or twice per year, sometimes more, sometimes less. Thus, they are infrequent. The Company provides, for a fee, additional training and service calls to its customers and recognizes revenue at the time the training or service call is provided.

Generally, we enter into one-year license agreements with customers for the use of our pharmaceutical software products. We recognize revenue on these contracts when all the criteria are met. Most license agreements have a term of one year; however, from time to time, we enter into multi-year license agreements. We generally unlock and invoice software one year at a time for multi-year licenses. Therefore, revenue is recognized one year at a time. Certain of the Company's software products are housed and supported on the Company's computer networks. Software revenues for those products are included in income over the life of the contract.

We recognize revenue from collaboration research, revenue from grants and consortium memberships over their terms. For contract revenues based on actual hours incurred we recognize revenues when the work is performed. For fixed price contracts, we recognize contract study and other contract revenues using the percentage-of-completion method, depending upon how the contract studies are engaged, in accordance with ASC 605-35, "*Revenue Recognition – Construction-Type and Production-Type Contracts"*. To recognize revenue using the percentage-of-completion method, we must determine whether we meet the following criteria: 1) there is a long-term, legally enforceable contract, 2) it is possible to reasonably estimate the total project costs, and 3) it is possible to reasonably estimate the extent of progress toward completion.

Cash and Cash Equivalents

For purposes of the statements of cash flows, we consider all highly liquid investments purchased with original maturities of three months or less to be cash equivalents.

Accounts Receivable

We analyze the age of customer balances, historical bad-debt experience, customer creditworthiness, and changes in customer payment terms when making estimates of the collectability of the Company's trade accounts receivable balances. If we determine that the financial conditions of any of its customers deteriorated, whether due to customer-specific or general economic issues, an increase in the allowance may be made. Accounts receivable are written off when all collection attempts have failed. We have not experienced any bad debts in our pharmaceutical software and services business.

Capitalized Computer Software Development Costs

Software development costs are capitalized in accordance with FASB ASC 985-20, "Costs of Software to Be Sold Leased, or Marketed". Capitalization of software development costs begins upon the establishment of technological feasibility and is discontinued when the product is available for sale.

The establishment of technological feasibility and the ongoing assessment for recoverability of capitalized software development costs require considerable judgment by management with respect to certain external factors including, but not limited to, technological feasibility, anticipated future gross revenues, estimated economic life, and changes in software and hardware technologies. Capitalized computer software development costs are comprised primarily of salaries and direct payroll-related costs and the purchase or licensing of existing software to be used in the Company's software products.

Amortization of capitalized computer software development costs is provided on a product-by-product basis on the straight-line method over the estimated economic life of the products not to exceed five years. Amortization of software development costs amounted to $1,300,434, $1,096,967 and $981,066 for FY18, FY17 and FY16, respectively. We expect future amortization expense to vary due to increases in capitalized computer software development costs.

We test capitalized computer software development costs for recoverability whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

Property and Equipment

Property and equipment are recorded at cost, less accumulated depreciation and amortization. Depreciation and amortization are provided using the straight-line method over the estimated useful lives as follows:

Equipment	5 years
Computer equipment	3 to 7 years
Furniture and fixtures	5 to 7 years
Leasehold improvements	Shorter of life of asset or lease

Maintenance and minor replacements are charged to expense as incurred. Gains and losses on disposals are included in the results of operations.

Intangible Assets and Goodwill

The Company performs valuations of assets acquired and liabilities assumed on each acquisition accounted for as a business combination and recognizes the assets acquired and liabilities assumed at their acquisition date fair value. Acquired intangible assets include customer relationships, software, trade name, and non-compete agreements. The Company determines the appropriate useful life by performing an analysis of expected cash flows based on historical experience of the acquired businesses. Intangible assets are amortized over their estimated useful lives using the straight-line method, which approximates the pattern in which the majority of the economic benefits are expected to be consumed.

Goodwill represents the excess of the cost of an acquired entity over the fair value of the acquired net assets. Goodwill is not amortized, instead it is tested for impairment annually or when events or circumstances change that would indicate that goodwill might be impaired. Events or circumstances that could trigger an impairment review include, but are not limited to, a significant adverse change in legal factors or in the business climate, an adverse action or assessment by a regulator, unanticipated competition, a loss of key personnel, significant changes in the manner of the Company's use of the acquired assets or the strategy for the Company's overall business, significant negative industry or economic trends or significant under-performance relative to expected historical or projected future results of operations.

Goodwill is tested for impairment at the reporting unit level, which is one level below or the same as an operating segment. As of August 31, 2018, the Company determined that it has three reporting units, Simulations Plus, Cognigen Corporation and DILIsym Services, Inc. When testing goodwill for impairment, the Company first performs a qualitative assessment to determine whether it is necessary to perform step one of a two-step annual goodwill impairment test for each reporting unit. The Company is required to perform step one only if it concludes that it is more likely than not that a reporting unit's fair value is less than its carrying value. Should this be the case, the first step of the two-step process is to identify whether a potential impairment exists by comparing the estimated fair values of the Company's reporting units with their respective book values, including goodwill. If the estimated fair value of the reporting unit exceeds book value, goodwill is considered not to be impaired, and no additional steps are necessary. If, however, the fair value of the reporting unit is less than book value, then the second step is performed to determine if goodwill is impaired and to measure the amount of impairment loss, if any. The amount of the impairment loss is the excess of the carrying amount of the goodwill over its implied fair value. The estimate of implied fair value of goodwill is primarily based on an estimate of the discounted cash flows expected to result from that reporting unit, but may require valuations of certain internally generated and unrecognized intangible assets such as the Company's software, technology, patents and trademarks. If the carrying amount of goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized in an amount equal to the excess.

As of August 31, 2018, the balance of goodwill was attributed to two of the Company's reporting units Cognigen and DILIsym. Intangible assets subject to amortization are reviewed for impairment whenever events or circumstances indicate that the carrying amount of these assets may not be recoverable. The Company has not recognized any impairment charges during FY18, FY17 and FY16.

Reconciliation of Goodwill for FY18, FY17 and FY16:

	Cognigen	DILIsym	Total
Balance, August 31, 2015	4,789,248	–	4,789,248
Addition	–	–	–
Impairments	–	–	–
Balance, August 31, 2016	4,789,248	–	4,789,248
Addition	–	5,597,950	5,597,950
Impairments	–	–	–
Balance, August 31, 2017	4,789,248	5,597,950	10,387,198
Addition	–	–	–
Impairments	–	–	–
Balance, August 31, 2018	$4,789,248	$5,597,950	$10,387,198

Other Intangible Assets

The following table summarizes other intangible assets as of August 31, 2018:

	Amortization Period	Acquisition Value	Accumulated Amortization	Net book value
Customer relationships-Cognigen	Straight line 8 years	$1,100,000	$ 550,000	$550,000
Trade Name-Cognigen	None	500,000	0	500,000
Covenants not to compete-Cognigen	Straight line 5 years	50,000	40,000	10,000
Covenants not to compete-DILIsym	Straight line 4 years	80,000	25,000	55,000
Trade Name-DILIsym	None	860,000	0	860,000
Customer relationships-DILIsym	Straight line 8 years	1,900,000	237,500	1,662,500
		$4,490,000	$ 852,500	$3,637,500

Amortization expense for FY18, FY17, and FY16 was $357,500, $200,000, and $147,500, respectively.

Business Acquisitions

The Company accounted for the acquisition of Cognigen and DILIsym Services Inc. using the purchase method of accounting where the assets acquired and liabilities assumed are recognized based on their respective estimated fair values. The excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill. Determining the fair value of certain acquired assets and liabilities is subjective in nature and often involves the use of significant estimates and assumptions, including, but not limited to, the selection of appropriate valuation methodology, projected revenue, expenses and cash flows, weighted average cost of capital, discount rates, estimates of advertiser and publisher turnover rates and estimates of terminal values. Business acquisitions are included in the Company's consolidated financial statements as of the date of the acquisition.

Fair Value of Financial Instruments

Assets and liabilities recorded at fair value in the Condensed Balance Sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair value. The categories, as defined by the standard are as follows:

Level Input:	**Input Definition:**
Level I	Inputs are unadjusted, quoted prices for identical assets or liabilities in active markets at the measurement date.
Level II	Inputs, other than quoted prices included in Level I, that are observable for the asset or liability through corroboration with market data at the measurement date.

Level III	Unobservable inputs that reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date.

For certain of our financial instruments, including accounts receivable, accounts payable, contract payable, accrued payroll and other expenses, and accrued bonus to officer, the amounts approximate fair value due to their short maturities.

Research and Development Costs

Research and development costs are charged to expense as incurred until technological feasibility has been established. These costs consist primarily of salaries and direct payroll-related costs. It also includes purchased software and databases that were developed by other companies and incorporated into, or used in the development of, our final products.

Income Taxes

We utilize FASB ASC 740-10, “Income Taxes”, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns.

Under this method, deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. The provision for income taxes represents the tax payable for the period and the change during the period in deferred tax assets and liabilities.

Stock-Based Compensation

The Company accounts for stock options using the modified prospective method in accordance with FASB ASC 718-10, *“Compensation-Stock Compensation”*. Under this method, compensation costs include estimated grant date fair value of the awards amortized over the options’ vesting period. Stock-based compensation was $562,079, $585,018 and $347,077 for the fiscal years ended August 31, 2018, 2017 and 2016, respectively, and is included in the statements of operations as Consulting, Salaries, and Research and Development expense.

ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of August 31, 2018, and August 31, 2017, we had cash and cash equivalents of $9.40 million and $6.22 million, respectively. We do not hold any investments that are exposed to market risk related to changes in interest rates, which could adversely affect the value of our assets and liabilities, and we do not hold any instruments for trading purposes and investment. Some of our cash and cash equivalents are held in money market accounts; however, they are not exposed to market rate risk.

In the years ended August 31, 2018, 2017, and 2016 we sold $3.57 million, $2.75 million and $2.49 million, respectively, of software through representatives in certain Asian markets in local currencies. As a result, our financial position, results of operations, and cash flows can be affected by fluctuations in foreign currency exchange rates, particularly fluctuations in the yen and RMB exchange rates. These transactions give rise to receivables that are denominated in currencies other than the entity’s functional currency. The value of these receivables is subject to changes because the receivables may become worth more or less due to changes in currency exchange rates. The majority of our software license agreements are denominated in U.S. dollars. We record foreign gains and losses as they are realized. We mitigate our risk from foreign currency fluctuations by adjusting prices in our foreign markets on a periodic basis. We base these changes on market conditions while working closely with our representatives. We

do not hedge currencies or enter into derivative contracts.

ITEM 8 - FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See the financial statements included elsewhere in this report beginning at page F-1, which are incorporated herein by reference.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and our Chief Financial Officer, after evaluating our “disclosure controls and procedures” (as defined in Securities Exchange Act of 1934 (the “Exchange Act”) Rules 13a-15(e) and 15d-15(e) as of the end of the period covered by this Annual Report on Form 10-K (the “Evaluation Date”), have concluded that as of the Evaluation Date, our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and to ensure that information required to be disclosed by us in such reports is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, where appropriate, to allow timely decisions regarding required disclosure.

Management Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. GAAP. Management assessed our internal control over financial reporting as of August 31, 2018, the end of our fiscal year. Management based its assessment on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment.

Based on this assessment, management has concluded that our internal control over financial reporting was effective as of the end of the fiscal year to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external reporting purposes in accordance with U.S. GAAP. We reviewed the results of management's assessment with the Audit Committee of our Board of Directors.

Our independent registered public accounting firm, Rose Snyder and Jacobs LLP, independently assessed the effectiveness of the Company's internal control over financial reporting, as stated in the firm's attestation report, which is included within Part II, Item 8 of this Form 10-K.

Inherent Limitations on Effectiveness of Controls

Our management, including the CEO and CFO, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well-designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of the effectiveness of controls to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in Internal Control Over Financial Reporting

No change in the Company's internal controls over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act) occurred during the Company's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B - OTHER INFORMATION

None.

PART III

ITEM 10 – DIRECTORS, AND EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Information required by Item 10 is incorporated by reference from the sections entitled “Board Matters and Corporate Governance,” “Election of Directors,” “Executive Compensation and Other Information,” and “Security Ownership of Certain Beneficial Owners and Management” in our definitive proxy statement on Schedule 14A to be distributed in connection with our 2017 Annual Shareholders’ Meeting (the “Proxy Statement”).

There have been no material changes to the procedures by which security holders may recommend nominees to our board of directors since we last described such procedures.

We adopted a Corporate Code of Ethics which is posted on our website: www.simulations-plus.com.

ITEM 11 – EXECUTIVE COMPENSATION

The information required by Item 11 is incorporated by reference from the sections entitled “Executive Compensation and Other Information” and “Board Matters and Corporate Governance” in the Proxy Statement.

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

The information required by Item 12 is incorporated by reference from the sections entitled “Security Ownership of Certain Beneficial Owners and Management” and “Executive Compensation and Other Information” in the Proxy Statement.

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

The information required by Item 13 is incorporated by reference from the subsection entitled “Certain Relationships and Related Transactions; Transactions with Related Persons” and the section entitled “Board Matters and Corporate Governance” in the Proxy Statement.

ITEM 14 – PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by Item 14 is incorporated by reference from the section of the proposal entitled “Ratification of Selection of Independent Registered Public Accounting Firm” in the Proxy Statement.

PART IV

ITEM 15 – EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)

(1) Financial Statements. The consolidated financial statements are included in this Annual Report on Form 10-K beginning on page F-1.

(2) Financial Statement Schedules. All financial statement schedules have been omitted since the information is either not applicable or required or was included in the financial statements or notes included in this Annual Report on Form 10-K.

(3) List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits. The following exhibits are filed or furnished with this report. Those exhibits marked with a (†) refer to management contracts or compensatory plans or arrangements.

EXHIBIT NUMBER	DESCRIPTION
2.1 (4)^	Agreement and Plan of Merger, dated July 23, 2014, by and among the Company, Cognigen Corporation and the other parties thereto.
3.1 (2)	Articles of Incorporation of the Company.
3.2 (2)	Amended and Restated Bylaws of the Company.
4.1 (1)	Form of Common Stock Certificate.
4.2 (1)	Share Exchange Agreement.
10.1 (1) (†)	The Company's 1996 Stock Option Plan and forms of agreements relating thereto.
10.2 (3) (†)	The Company's 2007 Stock Option Plan, as amended.
10.3 (10)	Second Amendment to Lease by and between the Company and Crest Development LLC, dated as of May 1, 2016.
10.4 (5) (†)	Employment Agreement by and between the Company and Walter S. Woltosz, dated as of August 8, 2016.
10.5 (6)	Form of Indemnification Agreement.

10.6 (8)	2017 Equity Incentive Plan.
10.7 (7)	Stock Purchase Agreement by and among Simulation Plus, Inc., DILIsym Services, Inc., The Shareholders' Representative and The Shareholders of DILIsym Services, Inc., dated as of May 1, 2017.
10.8 (9)(†)	Employment Agreement by and between the Company and Walter S. Woltosz, dated as of September 1, 2017.
10.9 (9) (†)	Employment Agreement by and between the Company and John DiBella, dated as of September 1, 2017.
10.10 (9) (†)	Employment Agreement by and between the Company and Thaddeus H Grasela Jr., dated as of September 2, 2017.
10.11 (11) (†)	Employment Agreement by and between the Company and Shawn O'Connor dated June 26, 2018
21.1 *	List of Subsidiaries.
23.1 *	Consent of Independent Registered Public Accounting Firm.
31.1 *	Section 302 – Certification of the Principal Executive Officer.
31.2 *	Section 302 – Certification of the Principal Financial Officer.
32.1 *	Section 906 – Certification of the Chief Executive Office and Chief Financial Officer.
101.INS **	XBRL Instance Document.
101.SCH **	XBRL Taxonomy Extension Schema Document.
101.CAL **	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF **	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB **	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE **	XBRL Taxonomy Extension Presentation Linkbase Document.

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^ Schedules and exhibits omitted pursuant to Item 601(b)(2) of Registration S-K. The registrant agrees to furnish supplementally a copy of any omitted schedule to the SEC upon request.

* Filed herewith.

** The XBRL related information in Exhibit 101 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability of that section and shall not be incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing or document.

(1) Incorporated by reference to the Company's Registration Statement on Form SB-2 (Registration No. 333-6680) filed on March 25, 1997.

(2) Incorporated by reference to an exhibit to the Company's Form 10-K for the fiscal year ended August 31, 2010.

(3) Incorporated by reference to an exhibit to the Company's Form 10-Q filed April 9, 2014.

(4) Incorporated by reference to an exhibit to the Company's Form 8-K/A filed November 18, 2014.

(5) Incorporated by reference to an exhibit to the Company's Form 8-K filed August 11, 2016.

(6) Incorporated by reference to an exhibit to the Company's Form 8-K filed August 10, 2016.

(7) Incorporated by reference to an exhibit to the Company's Form 10-Q filed July 10, 2017.

(8) Incorporated by reference to Appendix A to the Company's Schedule 14A filed December 29. 2016.

(9) Incorporated by reference to an exhibit to the Company's Form 8-K filed September 6, 2017.

(10) Incorporated by reference to an exhibit to the Company's Form 10-K for the fiscal year ended August 31, 2016.

(11) Incorporated by reference to an exhibit to the Company's Form 10-Q filed July 10, 2018.

(c) Financial Statement Schedule.

See Item 15(a)(2) above.

the Fund fails to maintain the asset coverage requirements specified under the 1940 Act on a quarterly valuation date and such failure is not cured on or before 60 days, in the case of the Fixed Rate Preferred Shares, or 10 business days, in the case of the Variable Rate Preferred Shares, following such failure; or

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the Fund fails to maintain the asset coverage requirements as calculated in accordance with the applicable rating agency guidelines as of any monthly valuation date, and such failure is not cured on or before 10 business days after such valuation date.

The redemption price for preferred shares subject to mandatory redemption will be the liquidation preference, as stated in the Prospectus Supplement accompanying the issuance of such preferred shares, plus an amount equal to any accumulated but unpaid distributions (whether or not earned or declared) to the date fixed for redemption, plus (in the case of Variable Rate Preferred Shares having a dividend period of more than one year) any applicable redemption premium determined by the Board of Trustees and included in the Statement of Preferences.

The number of preferred shares that will be redeemed in the case of a mandatory redemption will equal the minimum number of outstanding preferred shares, the redemption of which, if such redemption had occurred immediately prior to the opening of business on the applicable cure date, would have resulted in the relevant asset coverage requirement having been met or, if the required asset coverage cannot be so restored, all of the preferred shares. In the event that preferred shares are redeemed due to a failure to satisfy the 1940 Act asset coverage requirements, the Fund may, but is not required to, redeem a sufficient number of preferred shares so that the Fund s assets exceed the asset coverage requirements under the 1940 Act after the redemption by 10% (that is, 220% asset coverage). In the event that preferred shares are redeemed due to a failure to satisfy applicable rating agency guidelines, the Fund may, but is not required to, redeem a sufficient number of preferred shares so that the Fund s discounted portfolio value (as determined in accordance with the applicable rating agency guidelines) after redemption exceeds the asset coverage requirements of each applicable rating agency by up to 10% (that is, 110% rating agency asset coverage). In addition, as discussed under Optional Redemption of the Preferred Shares below, the Fund generally may redeem Variable Rate Preferred Shares subject to a variable rate, in whole or in part, at its option at any time (usually on a dividend or distribution payment date), other than during a non-call period.

If the Fund does not have funds legally available for the redemption of, or is otherwise unable to redeem, all the preferred shares to be redeemed on any redemption date, the Fund will redeem on such redemption date that number of shares for which it has legally available funds, or is otherwise able to redeem, from the holders whose shares are to be redeemed ratably on the basis of the redemption price of such shares, and the remainder of those shares to be redeemed will be redeemed on the earliest practicable date on which the Fund will have funds legally available for the redemption of, or is otherwise able to redeem, such shares upon written notice of redemption.

If fewer than all of the Fund s outstanding preferred shares are to be redeemed, the Fund, at its discretion and subject to the limitations of its Governing Documents and the 1940 Act, will select the one or more series of preferred shares from which shares will be redeemed and the amount of preferred shares to be redeemed from each such series. If less than all preferred shares of a series are to be redeemed, such redemption will be made as among the holders of that series pro rata in accordance with the respective number of shares of such series held by each such holder on the record date for such redemption (or by such other equitable method as the Fund may determine). If fewer than all the preferred shares held by any holder are to be redeemed, the notice of redemption mailed to such holder will specify the number of shares to be redeemed from such holder, which may be expressed as a percentage of shares held on the applicable record date.

Optional Redemption of Fixed Rate Preferred Shares. Fixed Rate Preferred Shares will not be subject to optional redemption by the Fund until the date, if any, specified in the applicable Prospectus Supplement, unless such redemption is necessary, in the judgment of the Fund, to maintain the Fund s status as a regulated investment company under the Code. Commencing on such date and thereafter, the Trust may at any time redeem such Fixed Rate Preferred Shares in whole or in part for cash at a redemption price per share equal to the initial liquidation preference per share plus accumulated and unpaid distributions (whether or not earned or declared) to the redemption date. Such

redemptions are subject to the notice requirements set forth under Redemption Procedures and the limitations of the Governing Documents and 1940 Act.

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Optional Redemption of Variable Rate Preferred Shares. The Fund generally may redeem Variable Rate Preferred Shares, if issued, in whole or in part, at its option at any time (usually on a dividend or distribution payment date), other than during a non-call period. The Fund may designate a non-call period during a dividend period of more than seven days. In the case of such preferred shares having a dividend period of one year or less, the redemption price per share will equal the initial liquidation preference plus an amount equal to any accumulated but unpaid distributions thereon (whether or not earned or declared) to the redemption date, and in the case of such Preferred Shares having a dividend period of more than one year, the redemption price per share will equal the initial liquidation preference plus any redemption premium applicable during such dividend period. Such redemptions are subject to the notice requirements set forth under Redemption Procedures and the limitations of the Governing Documents and 1940 Act.

Redemption Procedures. A notice of redemption with respect to an optional redemption will be given to the holders of record of preferred shares selected for redemption not less than 15 days (subject to NYSE requirements), in the case of Fixed Rate Preferred Shares, and not less than seven days in the case of Variable Rate Preferred Shares, nor, in both cases, more than 40 days prior to the date fixed for redemption. Preferred shareholders may receive shorter notice in the event of a mandatory redemption. Each notice of redemption will state (i) the redemption date, (ii) the number or percentage of preferred shares to be redeemed (which may be expressed as a percentage of such shares outstanding), (iii) the CUSIP number(s) of such shares, (iv) the redemption price (specifying the amount of accumulated distributions to be included therein), (v) the place or places where such shares are to be redeemed, (vi) that distributions on the shares to be redeemed will cease to accumulate on such redemption date, (vii) the provision of the Statement of Preferences, as applicable, under which the redemption is being made and (viii) any conditions precedent to such redemption. No defect in the notice of redemption or in the mailing thereof will affect the validity of the redemption proceedings, except as required by applicable law.

The holders of any preferred shares, whether subject to a variable or fixed rate, will not have the right to redeem any of their shares at their option.

Liquidation Preference. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Fund, the holders of preferred shares will be entitled to receive a preferential liquidating distribution, which is expected to equal the original purchase price per preferred share plus accumulated and unpaid dividends, whether or not declared, before any distribution of assets is made to holders of common shares. After payment of the full amount of the liquidating distribution to which they are entitled, the holders of preferred shares will not be entitled to any further participation in any distribution of assets by the Fund.

Voting Rights. The 1940 Act requires that the holders of any preferred shares, voting separately as a single class, have the right to elect at least two Trustees at all times. The remaining Trustees will be elected by holders of common shares and preferred shares, voting together as a single class. In addition, subject to the prior rights, if any, of the holders of any other class of senior securities outstanding, the holders of any preferred shares have the right to elect a majority of the Trustees at any time two years dividends on any preferred shares are unpaid. The 1940 Act also requires that, in addition to any approval by shareholders that might otherwise be required, the approval of the holders of a majority of any outstanding preferred shares, voting separately as a class, would be required to (i) adopt any plan of reorganization that would adversely affect the preferred shares, and (ii) take any action requiring a vote of security holders under Section 13(a) of the 1940 Act, including, among other things, changes in the Fund s subclassification as a closed-end investment company to an open-end company or changes in its fundamental investment restrictions. As a result of these voting rights, the Fund s ability to take any such actions may be impeded to the extent that there are any preferred shares outstanding. The Board of Trustees presently intends that, except as otherwise indicated in this prospectus and except as otherwise required by applicable law, holders of preferred shares will have equal voting rights with holders of common shares (one vote per share, unless otherwise required by the 1940 Act) and will vote together with holders of common shares as a single class.

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The affirmative vote of the holders of a majority of the outstanding preferred shares, voting as a separate class, will be required to amend, alter or repeal any of the preferences, rights or powers of holders of preferred shares so as to affect materially and adversely such preferences, rights or powers, or to increase or decrease the authorized number of preferred shares. The class vote of holders of preferred shares described above will in each case be in addition to any other vote required to authorize the action in question.

The foregoing voting provisions will not apply to any preferred shares if, at or prior to the time when the act with respect to which such vote otherwise would be required will be effected, such shares will have been redeemed or called for redemption and sufficient cash or cash equivalents provided to the applicable paying agent to effect such redemption.

Book Entry. Fixed Rate Preferred Shares will initially be held in the name of Cede & Co. as nominee for DTC. The Fund will treat Cede & Co. as the holder of record of preferred shares for all purposes. In accordance with the procedures of DTC, however, purchasers of Fixed Rate Preferred Shares will be deemed the beneficial owners of stock purchased for purposes of dividends, voting and liquidation rights.

Variable Rate Preferred Shares will initially be held by the auction agent as custodian for Cede & Co., in whose name the Variable Rate Preferred Shares will be registered. The Fund will treat Cede & Co. as the holder of record of the Variable Rate Preferred Shares for all purposes.

ANTI-TAKEOVER PROVISIONS OF THE FUND S GOVERNING DOCUMENTS

The Fund presently has provisions in its Governing Documents which could have the effect of limiting, in each case, (i) the ability of other entities or persons to acquire control of the Fund, (ii) the Fund s freedom to engage in certain transactions or (iii) the ability of the Fund s Trustees or shareholders to amend the Governing Documents or effectuate changes in the Fund s management. These provisions of the Governing Documents of the Fund may be regarded as anti-takeover provisions. The Board of Trustees of the Fund is divided into three classes, each having a term of no more than three years (except, to ensure that the term of a class of the Fund s Trustees expires each year, one class of the Fund s Trustees will serve an initial one-year term and three-year terms thereafter and another class of its Trustees will serve an initial two-year term and three-year terms thereafter). Each year the term of one class of Trustees will expire. Accordingly, only those Trustees in one class may be changed in any one year, and it would require a minimum of two years to change a majority of the Board of Trustees. Such system of electing Trustees may have the effect of maintaining the continuity of management and, thus, make it more difficult for the shareholders of the Fund to change the majority of Trustees. See Management of the Fund Trustees and Officers in the SAI. A trustee of the Fund may be removed with or without cause by two-thirds of the remaining Trustees and, without cause, by 662/3% of the votes entitled to be cast for the election of such Trustees. Special voting requirements of 75% of the outstanding voting shares (in addition to any required class votes) apply to certain mergers or a sale of all or substantially all of the Fund s assets, liquidation, conversion of the Fund into an open-end fund or interval fund and amendments to several provisions of the Declaration of Trust, including the foregoing provisions. In addition, after completion of the offering, 80% of the holders of the outstanding voting securities of the Fund voting as a class is generally required in order to authorize any of the following transactions:

merger or consolidation of the Fund with or into any other entity;

issuance of any securities of the Fund to any person or entity for cash, other than pursuant to the Dividend and Reinvestment Plan or any offering if such person or entity acquires no greater percentage of the securities offered than the percentage beneficially owned by such person or entity immediately prior to such offering or, in the case of a class or series not then beneficially owned by such person or entity, the percentage of common shares beneficially owned by such person or entity immediately prior to such offering;

sale, lease or exchange of all or any substantial part of the assets of the Fund to any entity or person (except assets having an aggregate fair market value of less than $5,000,000);

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sale, lease or exchange to the Fund, in exchange for securities of the Fund, of any assets of any entity or person (except assets having an aggregate fair market value of less than $5,000,000); or

the purchase of the Fund s common shares by the Fund from any person or entity other than pursuant to a tender offer equally available to other shareholders in which such person or entity tenders no greater percentage of common shares than are tendered by all other shareholders; if such person or entity is directly, or indirectly through affiliates, the beneficial owner of more than 5% of the outstanding shares of the Fund.

However, such vote would not be required when, under certain conditions, the Board of Trustees approves the transaction.

In addition, shareholders have no authority to adopt, amend or repeal By-Laws. The Board of Trustees has authority to adopt, amend and repeal By-Laws consistent with the Declaration of Trust (including to require approval by the holders of a majority of the outstanding shares for the election of Trustees).

The provisions of the Governing Documents described above could have the effect of depriving the owners of shares in the Fund of opportunities to sell their shares at a premium over prevailing market prices, by discouraging a third party from seeking to obtain control of the Fund in a tender offer or similar transaction. The overall effect of these provisions is to render more difficult the accomplishment of a merger or the assumption of control by a principal shareholder.

The Governing Documents of the Fund are on file with the SEC. For the full text of these provisions, see Additional Information.

CLOSED-END FUND STRUCTURE

The Fund is a non-diversified, closed-end management investment company (commonly referred to as a closed-end fund). Closed-end funds differ from open-end funds (which are generally referred to as mutual funds) in that closed-end funds generally list their shares for trading on a stock exchange and do not redeem their shares at the request of the shareholder. This means that if you wish to sell your shares of a closed-end fund you must trade them on the market like any other stock at the prevailing market price at that time. In a mutual fund, if the shareholder wishes to sell shares of the fund, the mutual fund will redeem or buy back the shares at net asset value. Also, mutual funds generally offer new shares on a continuous basis to new investors, and closed-end funds generally do not. The continuous inflows and outflows of assets in a mutual fund can make it difficult to manage the fund s investments. By comparison, closed-end funds are generally able to stay more fully invested in securities that are consistent with their investment objectives, to have greater flexibility to make certain types of investments and to use certain investment strategies such as financial leverage and investments in illiquid securities.

Shares of closed-end funds often trade at a discount to their net asset value. Because of this possibility and the recognition that any such discount may not be in the interest of shareholders, the Fund s Board of Trustees might consider from time to time engaging in open-market repurchases, tender offers for shares or other programs intended to reduce a discount. We cannot guarantee or assure, however, that the Fund s Board of Trustees will decide to engage in any of these actions. Nor is there any guarantee or assurance that such actions, if undertaken, would result in the shares trading at a price equal or close to net asset value per share. The Board of Trustees might also consider converting the Fund to an open-end mutual fund, which would also require a supermajority vote of the shareholders of the Fund and a separate vote of any outstanding preferred shares. We cannot assure you that the Fund s common shares will not trade at a discount.

REPURCHASE OF COMMON SHARES

The Fund is a non-diversified, closed-end management investment company and as such its shareholders do not, and will not, have the right to require the Fund to repurchase their shares. The Fund, however, may repurchase its common shares from time to time as and when it deems such a repurchase advisable. The

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Board of Trustees has authorized such repurchases to be made when the Fund s common shares are trading at a discount from net asset value of 7.5% or more (or such other percentage as the Board of Trustees of the Fund may determine from time to time). Although the Board of Trustees has authorized such repurchases, the Fund is not required to repurchase its common shares. The Board of Trustees has not established a limit on the number of shares that could be purchased during such period. Pursuant to the 1940 Act, the Fund may repurchase its common shares on a securities exchange (provided that the Fund has informed its shareholders within the preceding six months of its intention to repurchase such shares) or pursuant to tenders and may also repurchase shares privately if the Fund meets certain conditions regarding, among other things, distribution of net income for the preceding fiscal year, status of the seller, price paid, brokerage commissions, prior notice to shareholders of an intention to purchase shares and purchasing in a manner and on a basis that does not discriminate unfairly against the other shareholders through their interest in the Fund.

When the Fund repurchases its common shares for a price below net asset value, the net asset value of the common shares that remain outstanding shares will be enhanced, but this does not necessarily mean that the market price of the outstanding common shares will be affected, either positively or negatively. The repurchase of common shares will reduce the total assets of the Fund available for investment and may increase the Fund s expense ratio.

NET ASSET VALUE

For purposes of determining the Fund s net asset value per share, portfolio securities listed or traded on a nationally recognized securities exchange or traded in the U.S. over-the-counter market for which market quotations are readily available are valued at the last quoted sale price or a market s official closing price as of the close of business on the day the securities are being valued. If there were no sales that day, the security is valued at the average of the closing bid and asked prices, or, if there were no asked prices quoted on such day, the security is valued at the most recently available price or, if the Board of Trustees so determines, by such other method as the Board of Trustees shall determine in good faith, to reflect its fair market value. Portfolio securities traded on more than one national securities exchange or market are valued according to the broadest and most representative market, as determined by the Investment Adviser.

Portfolio securities primarily traded on foreign markets are generally valued at the preceding closing values of such securities on the relevant market, but may be fair valued pursuant to procedures established by the Board of Trustees if market conditions change significantly after the close of the foreign market but prior to the close of business on the day the securities are being valued. Debt instruments with remaining maturities of 60 days or less that are not credit impaired are valued at amortized cost, unless the Board of Trustees determines such amount does not reflect the securities fair value, in which case these securities will be fair valued by or under the direction of the Board of Trustees. Debt instruments having a maturity greater than 60 days for which market quotations are readily available are valued at the average of the latest bid and asked prices. If there were no asked prices quoted on such day, the security is valued using the closing bid price. Futures contracts are valued at the closing settlement price of the exchange or board of trade on which the applicable contract is traded.

Securities and assets for which market quotations are not readily available are valued at their fair value as determined in good faith under procedures established by and under the general supervision of the Board of Trustees. Fair valuation methodologies and procedures may include, but are not limited to: analysis and review of available financial and non-financial information about the company; comparisons to the valuation and changes in valuation of similar securities, including a comparison of foreign securities to the equivalent U.S. dollar value ADR securities at the close of the U.S. exchange; and evaluation of any other information that could be indicative of the value of the security.

The Fund obtains valuations on the basis of prices provided by a pricing service approved by the Board of Trustees. All other investment assets, including restricted and not readily marketable securities, are valued in good faith at fair

value under procedures established by and under the general supervision and responsibility of the Fund s Board of Trustees.

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In addition, whenever developments in one or more securities markets after the close of the principal markets for one or more portfolio securities and before the time as of which the Fund determines its net asset value would, if such developments had been reflected in such principal markets, likely have more than a minimal effect on the Fund s net asset value per share, the Fund may fair value such portfolio securities based on available market information as of the time the Fund determines its net asset value.

NYSE Closings. The holidays (as observed) on which the NYSE is closed, and therefore days upon which shareholders cannot purchase or sell shares, currently are: New Year s Day, Martin Luther King, Jr. Day, Presidents Day, Good Friday, Memorial Day, Independence Day, Labor Day, Thanksgiving Day and Christmas Day and on the preceding Friday or subsequent Monday when a holiday falls on a Saturday or Sunday, respectively.

TAXATION

The following discussion is a brief summary of certain U.S. federal income tax considerations affecting the Fund and the purchase, ownership and disposition of the Fund s shares. A more complete discussion of the tax rules applicable to the Fund and its shareholders can be found in the SAI that is incorporated by reference into this prospectus. This discussion assumes you are a U.S. person and that you hold your shares as capital assets. This discussion is based upon current provisions of the Code, the regulations promulgated thereunder and judicial and administrative authorities, all of which are subject to change or differing interpretations by the courts or the Internal Revenue Service (the IRS), possibly with retroactive effect. No attempt is made to present a detailed explanation of all U.S. federal tax concerns affecting the Fund and its shareholders (including shareholders owning large positions in the Fund).

The discussion set forth herein does not constitute tax advice and potential investors are urged to consult their own tax advisers to determine the tax consequences to them of investing in the Fund.

Taxation of the Fund

The Fund has elected to be treated and has qualified, and intends to continue to qualify annually, as a regulated investment company under Subchapter M of the Code. Accordingly, the Fund must, among other things, meet the following requirements regarding the source of its income and the diversification of its assets:

(i) The Fund must derive in each taxable year at least 90% of its gross income from the following sources, which are referred to herein as Qualifying Income : (a) dividends, interest (including tax-exempt interest), payments with respect to certain securities loans, and gains from the sale or other disposition of stock, securities or foreign currencies, or other income (including but not limited to gain from options, futures and forward contracts) derived with respect to its business of investing in such stock, securities or foreign currencies; and (b) interests in publicly traded partnerships that are treated as partnerships for U.S. federal income tax purposes and that derive less than 90% of their gross income from the items described in (a) above (each a Qualified Publicly Traded Partnership).

(ii) The Fund must diversify its holdings so that, at the end of each quarter of each taxable year (a) at least 50% of the market value of the Fund s total assets is represented by cash and cash items, U.S. government securities, the securities of other regulated investment companies and other securities, with such other securities limited, in respect of any one issuer, to an amount not greater than 5% of the value of the Fund s total assets and not more than 10% of the outstanding voting securities of such issuer and (b) not more than 25% of the market value of the Fund s total assets is invested in the securities (other than U.S. government securities and the securities of other regulated investment companies) of (I) any one issuer, (II) any two or more issuers that the Fund controls and that are determined to be engaged in the same business or similar or related trades or businesses or (III) any one or more Qualified Publicly Traded Partnerships.

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Income from the Fund s investments in grantor trusts and equity interest of MLPs that are not Qualified Publicly Traded Partnerships (if any) will be Qualifying Income to the extent it is attributable to items of income of such trust or MLP that would be Qualifying Income if earned directly by the Fund.

The Fund s investments in partnerships, including in Qualified Publicly Traded Partnerships, may result in the Fund being subject to state, local or foreign income, franchise or withholding tax liabilities.

As a regulated investment company, the Fund generally will not be subject to U.S. federal income tax on income and gains that the Fund distributes to its shareholders, provided that it distributes each taxable year at least the sum of (i) 90% of the Fund s investment company taxable income (which includes, among other items, dividends, interest and the excess of any net short-term capital gain over net long-term capital loss and other taxable income, other than any net long-term capital gain, reduced by deductible expenses) determined without regard to the deduction for dividends paid and (ii) 90% of the Fund s net tax-exempt interest income (the excess of its gross tax-exempt interest over certain disallowed deductions). The Fund intends to distribute substantially all of such income at least annually. The Fund will be subject to income tax at regular corporate rates on any taxable income or gains that it does not distribute to its shareholders.

The Code imposes a 4% nondeductible excise tax on the Fund to the extent the Fund does not distribute by the end of any calendar year an amount at least equal to the sum of (i) 98% of its ordinary income (not taking into account any capital gain or loss) for the calendar year and (ii) 98% of its capital gain in excess of its capital loss (adjusted for certain ordinary losses) for a one-year period generally ending on October 31 of the calendar year (unless an election is made to use the Fund s fiscal year). In addition, the minimum amounts that must be distributed in any year to avoid the excise tax will be increased or decreased to reflect any under-distribution or over-distribution, as the case may be, from the previous year. While the Fund intends to distribute any income and capital gain in the manner necessary to minimize imposition of the 4% excise tax, there can be no assurance that sufficient amounts of the Fund s taxable income and capital gain will be distributed to entirely avoid the imposition of the excise tax. In that event, the Fund will be liable for the excise tax only on the amount by which it does not meet the foregoing distribution requirement.

If for any taxable year the Fund does not qualify as a regulated investment company, all of its taxable income (including its net capital gain) will be subject to tax at regular corporate rates without any deduction for distributions to shareholders.

Taxation of Shareholders

Distributions paid to you by the Fund from its net realized long-term capital gains, if any, that the Fund designates as capital gains dividends (capital gain dividends) are taxable as long-term capital gains, regardless of how long you have held your common shares. All other dividends paid to you by the Fund (including dividends from short-term capital gains) from its current or accumulated earnings and profits (ordinary income dividends) are generally subject to tax as ordinary income.

Special rules apply, however, to ordinary income dividends paid to individuals with respect to taxable years beginning on or before December 31, 2010. If you are an individual, any such ordinary income dividend that you receive from the Fund generally will be eligible for taxation at the Federal rates applicable to long-term capital gains (currently at a maximum rate of 15%) to the extent that (i) the ordinary income dividend is attributable to qualified dividend income (i.e., generally dividends paid by U.S. corporations and certain foreign corporations) received by the Fund, (ii) the Fund satisfies certain holding period and other requirements with respect to the stock on which such qualified dividend income was paid and (iii) you satisfy certain holding period and other requirements with respect to your common shares. There can be no assurance as to what portion of the Fund s ordinary income dividends will constitute qualified dividend income.

Any distributions you receive that are in excess of the Fund s current or accumulated earnings and profits will be treated as a tax-free return of capital to the extent of your adjusted tax basis in your common shares, and thereafter as capital gain from the sale of common shares. The amount of any Fund distribution that is treated as a tax-free return of capital will reduce your adjusted tax basis in your common shares, thereby

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increasing your potential gain or reducing your potential loss on any subsequent sale or other disposition of your common shares.

Dividends and other taxable distributions are taxable to you even though they are reinvested in additional common shares of the Fund. Dividends and other distributions paid by the Fund are generally treated under the Code as received by you at the time the dividend or distribution is made. If, however, the Fund pays you a dividend in January that was declared in the previous October, November or December and you were the shareholder of record on a specified date in one of such months, then such dividend will be treated for tax purposes as being paid by the Fund and received by you on December 31 of the year in which the dividend was declared.

The Fund will send you information after the end of each year setting forth the amount and tax status of any distributions paid to you by the Fund.

The sale or other disposition of common shares of the Fund will generally result in capital gain or loss to you, and will be long-term capital gain or loss if you have held such common shares for more than one year at the time of sale. Any loss upon the sale or exchange of common shares held for six months or less will be treated as long-term capital loss to the extent of any capital gain dividends received (including amounts credited as an undistributed capital gain dividend) by you with respect to such common shares. Any loss you realize on a sale or exchange of common shares will be disallowed if you acquire other common shares (whether through the automatic reinvestment of dividends or otherwise) within a 61-day period beginning 30 days before and ending 30 days after your sale or exchange of the common shares. In such case, your tax basis in the common shares acquired will be adjusted to reflect the disallowed loss.

The Fund may be required to withhold, for U.S. federal backup withholding tax purposes, a portion of the dividends, distributions and redemption proceeds payable to shareholders who fail to provide the Fund (or its agent) with their correct taxpayer identification number (in the case of individuals, generally, their social security number) or to make required certifications, or who have been notified by the IRS that they are subject to backup withholding. Certain shareholders are exempt from backup withholding. Backup withholding is not an additional tax and any amount withheld may be refunded or credited against your U.S. federal income tax liability, if any, provided that you furnish the required information to the IRS.

CUSTODIAN, TRANSFER AGENT AND DIVIDEND DISBURSING AGENT

Mellon, located at 135 Santilli Highway, Everett, Massachusetts 02149, serves as the Custodian of the Fund s assets pursuant to a custody agreement. Under the custody agreement, the Custodian holds the Fund s assets in compliance with the 1940 Act. For its services, the Custodian will receive a monthly fee paid by the Fund based upon, among other things, the average value of the total assets of the Fund, plus certain charges for securities transactions and out-of-pocket expenses.

American Stock Transfer, located at 59 Maiden Lane, New York, New York 10038, serves as the Fund s dividend disbursing agent, as agent under the Fund s Plan and as transfer agent and registrar for the common shares of the Fund.

PLAN OF DISTRIBUTION

We may sell the shares, being offered hereby in one or more of the following ways from time to time:

to underwriters or dealers for resale to the public or to institutional investors;

directly to institutional investors;

directly to a limited number of purchasers or to a single purchaser;

through agents to the public or to institutional investors; or

through a combination of any of these methods of sale.

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The prospectus supplement with respect to each series of securities will state the terms of the offering of the securities, including:

- the offering terms, including the name or names of any underwriters, dealers or agents;
- the purchase price of the securities and the net proceeds to be received by us from the sale;
- any underwriting discounts or agency fees and other items constituting underwriters or agents compensation;
- any initial public offering price;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any securities exchange on which the securities may be listed.

If we use underwriters or dealers in the sale, the securities will be acquired by the underwriters or dealers for their own account and may be resold from time to time in one or more transactions, including;

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

Any initial public offering price and any discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time.

If underwriters are used in the sale of any securities, the securities may be either offered to the public through underwriting syndicates represented by managing underwriters, or directly by underwriters. Generally, the underwriters obligations to purchase the securities will be subject to certain conditions precedent. The underwriters will be obligated to purchase all of the securities if they purchase any of the securities.

If indicated in an applicable prospectus supplement, we may sell the securities through agents from time to time. The applicable prospectus supplement will name any agent involved in the offer or sale of the securities and any commissions we pay to them. Generally, any agent will be acting on a best efforts basis for the period of its appointment. We may authorize underwriters, dealers or agents to solicit offers by certain purchasers to purchase the securities from us at the public offering price set forth in the applicable prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The delayed delivery contracts will be subject only to those conditions set forth in the applicable prospectus supplement, and the applicable prospectus supplement will set forth any commissions we pay for solicitation of these delayed delivery contracts.

Offered securities may also be offered and sold, if so indicated in the applicable prospectus supplement, in connection with a remarketing upon their purchase, in accordance with a redemption or repayment pursuant to their terms, or otherwise, by one or more remarketing firms, acting as principals for their own accounts or as agents for us. Any

remarketing firm will be identified and the terms of its agreements, if any, with us and its compensation will be described in the applicable prospectus supplement.

Agents, underwriters and other third parties described above may be entitled to indemnification by us against certain civil liabilities under the Securities Act, or to contribution with respect to payments which the agents or underwriters may be required to make in respect thereof. Agents, underwriters and such other third parties may be customers of, engage in transactions with, or perform services for us in the ordinary course of business.

Each series of securities will be a new issue of securities and will have no established trading market other than our common shares and Preferred Shares, which are listed on the NYSE. Any common shares sold will be listed on NYSE, upon official notice of issuance. The securities, other than the common shares, may or may not be listed on a national securities exchange. Any underwriters to whom securities are sold by us for public offering and sale may make a market in the securities, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice.

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LEGAL MATTERS

Certain legal matters will be passed on by Skadden, Arps, Slate, Meagher & Flom LLP, counsel to the Fund in connection with the offering of the Fund s shares.

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

PricewaterhouseCoopers LLP serves as the independent registered public accounting firm of the Fund and audits the financial statements of the Fund. PricewaterhouseCoopers LLP is located at 300 Madison Avenue, New York, New York 10017.

ADDITIONAL INFORMATION

The Fund is subject to the informational requirements of the Securities Exchange Act of 1934, as amended, and the 1940 Act, and in accordance therewith files reports and other information with the SEC. Reports, proxy statements and other information filed by the Fund with the SEC pursuant to the informational requirements of such Acts can be inspected and copied at the public reference facilities maintained by the SEC, 100 F Street, N.E., Washington, D.C. 20549. The SEC maintains a web site at http://www.sec.gov containing reports, proxy and information statements and other information regarding registrants, including the Fund, that file electronically with the SEC.

The common shares are listed on the NYSE under the symbol GGN. The Preferred Shares are listed on the NYSE under the symbol GGN PrA. Reports, proxy statements and other information concerning the Fund and filed with the SEC by the Fund will be available for inspection at the NYSE, 11 Wall Street, New York, New York, 10005.

This prospectus constitutes part of a Registration Statement filed by the Fund with the SEC under the Securities Act of 1933 and the 1940 Act. This prospectus omits certain of the information contained in the Registration Statement, and reference is hereby made to the Registration Statement and related exhibits for further information with respect to the Fund and the common shares offered hereby. Any statements contained herein concerning the provisions of any document are not necessarily complete, and, in each instance, reference is made to the copy of such document filed as an exhibit to the Registration Statement or otherwise filed with the SEC. Each such statement is qualified in its entirety by such reference. The complete Registration Statement may be obtained from the SEC upon payment of the fee prescribed by its rules and regulations or free of charge through the SEC s web site (http://www.sec.gov).

PRIVACY PRINCIPLES OF THE FUND

The Fund is committed to maintaining the privacy of its shareholders and to safeguarding their non-public personal information. The following information is provided to help you understand what personal information the Fund collects, how the Fund protects that information and why, in certain cases, the Fund may share information with select other parties.

Generally, the Fund does not receive any non-public personal information relating to its shareholders, although certain non-public personal information of its shareholders may become available to the Fund. The Fund does not disclose any non-public personal information about its shareholders or former shareholders to anyone, except as permitted by law or as is necessary in order to service shareholder accounts (for example, to a transfer agent or third party administrator).

The Fund restricts access to non-public personal information about its shareholders to employees of the Fund, the Investment Adviser, and its affiliates with a legitimate business need for the information. The Fund maintains physical, electronic and procedural safeguards designed to protect the non-public personal information of its shareholders.

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An SAI dated as of April 3, 2009, has been filed with the SEC and is incorporated by reference in this prospectus. An SAI may be obtained without charge by writing to the Fund at its address at One Corporate Center, Rye, New York 10580-1422 or by calling the Fund toll-free at (800) GABELLI (422-3554). The Table of Contents of the SAI is as follows:

No person has been authorized to give any information or to make any representations in connection with this offering other than those contained in this Prospectus in connection with the offer contained herein, and, if given or made, such other information or representations must not be relied upon as having been authorized by the Fund, the Investment Adviser or the underwriters. Neither the delivery of this Prospectus nor any sale made hereunder will, under any circumstances, create any implication that there has been no change in the affairs of the Fund since the date hereof or that the information contained herein is correct as of any time subsequent to its date. This Prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the securities to which it relates. This Prospectus does not constitute an offer to sell or the solicitation of an offer to buy such securities in any circumstance in which such an offer or solicitation is unlawful.

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$350,000,000

Common Shares of Beneficial Interest
Preferred Shares of Beneficial Interest

PROSPECTUS

April 3, 2009

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Up to 180,000 Common Shares of Beneficial Interest

PROSPECTUS SUPPLEMENT

June 2, 2009