

SIMULATIONS PLUS INC  
Form 10-Q  
July 10, 2017

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, DC 20549**

**FORM 10-Q**

Quarterly Report Pursuant to Section 13 or 15(d) of the Security Exchange Act of 1934 for the quarterly period ended **May 31, 2017**

OR

Transmission Report Pursuant to Section 13 or 15(d) of the Security Exchange Act of 1937 for the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: **001-32046**

**Simulations Plus, Inc.**

(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 10<sup>th</sup> Street West**  
**Lancaster, CA 93534-7059**

(Address of principal executive offices including zip code)

**(661) 723-7723**  
(Registrant's telephone number, including area code)

Edgar Filing: SIMULATIONS PLUS INC - Form 10-Q

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

See the definitions of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer	Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company
Emerging Growth Company	

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.

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

The number of shares outstanding of the registrant’s common stock, par value \$0.001 per share, as of July 10, 2017 was 17,245,346; no shares of preferred stock were outstanding.



**Simulations Plus, Inc.**

**FORM 10-Q**

**For the Quarterly Period Ended May 31, 2017**

Table of Contents

**PART I. FINANCIAL INFORMATION**

	<u>Page</u>
Item 1. <u>Condensed Consolidated Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets at May 31, 2017 (unaudited) and August 31, 2016 (audited)</u>	3
<u>Condensed Consolidated Statements of Operations for the three months and nine months ended May 31, 2017 and 2016 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended May 31, 2017 and 2016 (unaudited)</u>	5
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Result of Operations</u>	16
<u>General</u>	16
<u>Results of Operations</u>	23
<u>Liquidity and Capital Resources</u>	25
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	26
Item 4. <u>Controls and Procedures</u>	26

**PART II. OTHER INFORMATION**

Item 1. <u>Legal Proceedings</u>	26
Item 1A. <u>Risk Factors</u>	27
Item 2. <u>Changes in Securities</u>	36

Item 3. <u>Defaults upon Senior Securities</u>	36
Item 4. <u>Mine Safety Disclosures</u>	36
Item 5. <u>Other Information</u>	36
Item 6. <u>Exhibits</u>	36
<u>Signature</u>	38

**Part I. Financial Information****Item 1. Condensed Consolidated Financial Statements****SIMULATIONS PLUS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

	(Unaudited) May 31,	(Audited) August 31,
	2017	2016
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$8,248,197	\$8,030,284
Accounts receivable, net of allowance for doubtful accounts of \$0	5,010,589	3,009,517
Revenues in excess of billings	1,130,154	694,131
Prepaid income taxes	241,540	555,486
Prepaid expenses and other current assets	304,408	410,811
Total current assets	14,934,888	12,700,229
Long-term assets		
Capitalized computer software development costs, net of accumulated amortization of \$9,477,930 and \$8,613,487	4,077,144	4,013,127
Property and equipment, net (note 3)	257,552	256,381
Intellectual property, net of accumulated amortization of \$1,864,375 and \$1,408,750	4,210,625	4,666,250
Other intangible assets net of accumulated amortization of \$405,625 and \$295,000	1,244,375	1,355,000
Goodwill	4,789,248	4,789,248
Other assets	34,082	34,082
Total assets	\$29,547,914	\$27,814,317
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$211,645	\$108,111
Accrued payroll and other expenses	647,203	481,610
Accrued bonuses to officers	45,750	121,000
Other current liabilities	-	8,274
Current portion - Contracts payable (note 4)	-	1,000,000
Billings in excess of revenues	313,399	230,100
Deferred revenue	48,964	176,422
Total current liabilities	1,266,961	2,125,517
Long-term liabilities		
Deferred income taxes	3,055,465	2,956,206

Edgar Filing: SIMULATIONS PLUS INC - Form 10-Q

Total liabilities	4,322,426	5,081,723
<b>Commitments and contingencies</b> (note 5)		
<b>Shareholders' equity</b> (note 6)		
Preferred stock, \$0.001 par value 10,000,000 shares authorized no shares issued and outstanding	—	—
Common stock, \$0.001 par value 50,000,000 shares authorized 17,242,510 and 17,225,478 shares issued and outstanding	7,244	7,227
Additional paid-in capital	11,816,573	11,376,007
Retained earnings	13,401,671	11,349,360
Total shareholders' equity	25,225,488	22,732,594
	\$—	—
Total liabilities and shareholders' equity	\$29,547,914	\$27,814,317

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

**SIMULATIONS PLUS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****For the three and nine months ended May 31, 2017 and 2016**

	Three months ended (Unaudited)		Nine months ended (Unaudited)	
	2017	2016	2017	2016
Net Revenues	\$6,748,518	\$6,012,193	\$17,872,044	\$16,014,539
Cost of revenues	1,444,764	1,194,815	4,334,699	3,541,903
Gross margin	5,303,754	4,817,378	13,537,345	12,472,636
Operating expenses				
Selling, general, and administrative	1,954,871	1,680,707	5,766,563	5,079,985
Research and development	253,799	348,427	952,635	1,161,124
Total operating expenses	2,208,670	2,029,134	6,719,198	6,241,109
Income from operations	3,095,084	2,788,244	6,818,147	6,231,527
Other income (expense)				
Interest income	4,663	4,553	13,548	13,507
Gain (loss) on currency exchange	(14,913 )	7,733	5,573	(35,490 )
Total other income (expense)	(10,250 )	12,286	19,121	(21,983 )
Income before provision for income taxes	3,084,834	2,800,530	6,837,268	6,209,544
Provision for income taxes	(1,004,805 )	(891,191 )	(2,199,914 )	(2,048,383 )
Net Income	\$2,080,029	\$1,909,339	\$4,637,354	\$4,161,161
Earnings per share				
Basic	\$0.12	\$0.11	\$0.27	\$0.24
Diluted	\$0.12	\$0.11	\$0.27	\$0.24
Weighted-average common shares outstanding				
Basic	17,241,891	17,028,634	17,233,470	17,000,228
Diluted	17,585,528	17,227,540	17,454,864	17,219,835

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



## SIMULATIONS PLUS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

For the nine months ended May 31, 2017 and 2016

	(Unaudited)	
	2017	2016
Cash flows from operating activities		
Net income	\$4,637,354	\$4,161,161
Adjustments to reconcile net income to net cash provided by operating activities		
Depreciation and amortization of property and equipment	116,348	148,442
Amortization of capitalized computer software development costs	864,443	735,579
Amortization of Intellectual Property	566,250	566,250
Stock-based compensation	355,365	234,616
Deferred income taxes	99,259	(4,910 )
(Increase) decrease in		
Accounts receivable	(2,001,072)	(2,988,866)
Revenues in excess of billings	(436,023 )	(244,772 )
Prepaid income taxes	313,946	(108,690 )
Prepaid expenses and other assets	106,403	93,554
Increase (decrease) in		
Accounts payable	103,534	(24,411 )
Accrued payroll and other expenses	165,593	81,212
Accrued bonus	(75,250 )	(30,250 )
Billings in excess of revenues	83,299	5,911
Accrued income taxes	-	(43,602 )
Other liabilities	(8,274 )	(14,894 )
Deferred revenue	(127,458 )	182,321
Net cash provided by operating activities	4,763,717	2,748,651
Cash flows used in investing activities		
Purchases of property and equipment	(117,519 )	(32,317 )
Capitalized computer software development costs	(928,460 )	(815,582 )
Net cash used in investing activities	(1,045,979)	(847,899 )
Cash flows used in financing activities		
Payment of dividends	(2,585,043)	(2,552,175)
Payments on Contracts Payable	(1,000,000)	(750,000 )
Proceeds from the exercise of stock options	85,218	129,831
Net cash used in financing activities	(3,499,825)	(3,172,344)
Net increase (decrease) in cash and cash equivalents	217,913	(1,271,592)
Cash and cash equivalents, beginning of year	8,030,284	8,551,275
Cash and cash equivalents, end of period	\$8,248,197	\$7,279,683

Supplemental disclosures of cash flow information

Income taxes paid	\$1,765,189	\$2,186,159
-------------------	-------------	-------------

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

**Simulations Plus, Inc.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

May 31, 2017 and 2016

(Unaudited)

**NOTE 1: GENERAL**

This report on Form 10-Q for the quarter ended May 31, 2017, should be read in conjunction with the Company's annual report on Form 10-K for the year ended August 31, 2016, filed with the Securities and Exchange Commission ("SEC") on November 14, 2016. As contemplated by the SEC under Article 8 of Regulation S-X, the accompanying consolidated financial statements and footnotes have been condensed and therefore do not contain all disclosures required by generally accepted accounting principles. The interim financial data are unaudited; however, in the opinion of Simulations Plus, Inc. ("we", "our", "us"), the interim data includes all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the results for the interim periods. Results for interim periods are not necessarily indicative of those to be expected for the full year.

Organization

Simulations Plus, Inc. ("Simulations Plus", "Lancaster") was incorporated on July 17, 1996. On September 2, 2014, Simulations Plus, Inc. acquired all of the outstanding equity interests of Cognigen Corporation ("Cognigen", "Buffalo") and Cognigen became a wholly owned subsidiary of Simulations Plus, Inc. (collectively, "Company", "we", "us", "our"), pursuant to the terms of that certain Agreement and Plan of Merger, dated as of July 23, 2014, by and between Simulations Plus and Cognigen (the "Merger Agreement").

Subsequent to May 31, 2017, on June 1, 2017 the Company acquired 100% of the stock of DILIsym Systems, Inc.

Lines of Business

The Company designs and develops pharmaceutical simulation software to promote cost-effective solutions to a number of problems in pharmaceutical research and in the education of pharmacy and medical students, and it provides consulting services to the pharmaceutical and chemical industries. The Company is also exploring developing software applications for defense and for health care outside of the pharmaceutical industry.

## NOTE 2: SIGNIFICANT ACCOUNTING POLICIES

### Principles of Consolidation

The consolidated financial statements include the accounts of Simulations Plus, Inc. and its wholly owned subsidiary, Cognigen Corporation. All significant intercompany accounts and transactions are eliminated in consolidation.

### Estimates

Our condensed consolidated financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America. 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 computer software development costs, valuation of stock options, and accounting for income taxes.

### Reclassifications

Certain numbers in the prior year have been reclassified to conform to the current year's presentation.

### Revenue Recognition

We recognize revenues related to software licenses and software maintenance in accordance with Financial Accounting Standard Board ("FASB") Accounting Standard 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 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.

6

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 multiyear licenses. Therefore, revenue is recognized one year at a time.

We recognize revenue from collaboration research and revenue from grants equally 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.

#### Capitalized Computer Software Development Costs

Software development costs are capitalized in accordance with 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 software development costs are comprised primarily of salaries and direct payroll-related costs and the purchase of existing software to be used in our software products.

Amortization of capitalized software development costs is calculated on a product-by-product basis on the straight-line method over the estimated economic life of the products (not to exceed five years, although all of our current software products have already been on the market for 7-15 years except for our newest PKPlus™ program, and we do not foresee an end-of-life for any of them at this point). Amortization of software development costs amounted to \$290,567 and \$241,042 for the three months ended May 31, 2017 and 2016 and \$864,443 and \$735,579 for the nine months ended May 31, 2017 and 2016, 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.

### Goodwill and indefinite-lived assets

Goodwill and indefinite-lived assets are not amortized, but are evaluated for impairment annually or when indicators of a potential impairment are present. Our impairment testing of goodwill is performed separately from our impairment testing of indefinite-lived intangibles. The annual evaluation for impairment of goodwill and indefinite-lived intangibles is based on valuation models that incorporate assumptions and internal projections of expected future cash flows and operating plans.

### 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:

<b>Level</b>	<b>Input Definition:</b>
<b>Input:</b>	
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, accrued payroll and other expenses, accrued bonus to officer, and accrued warranty and service costs, 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.

We follow guidance issued by the FASB with regard to our accounting for uncertainty in income taxes recognized in the financial statements. Such guidance prescribes a recognition threshold of more likely than not and a measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In making this assessment, a company must determine whether it is more likely than not that a tax position will be sustained upon examination, based solely on the technical merits of the position and must assume that the tax position will be examined by taxing authorities. Our policy is to include interest and penalties related to unrecognized tax benefits in income tax expense. Interest and penalties totaled \$ -0- and \$-0- for fiscal year 2017 and 2016, respectively. We file income tax returns with the IRS and various state jurisdictions and India.

#### Intellectual property

On February 28, 2012, we bought out the royalty agreement with Enslein Research of Rochester, New York. The cost of \$75,000 is being amortized over 10 years under the straight-line method. Amortization expense for each of the three-month periods ended May 31, 2017 and 2016 was \$1,875, and was \$3,750 for each of the nine-month periods ended May 31, 2017 and 2016. Accumulated amortization as of May 31, 2017 and August 31, 2016 was \$39,375 and \$33,750, respectively.

On May 15, 2014, we entered into a termination and non-assertion agreement with TSRL, Inc., pursuant to which the parties agreed to terminate an exclusive software licensing agreement entered into between the parties in 1997. As a result, the company obtained a perpetual right to use certain source code and data, and TSRL relinquished any rights and claims to any GastroPlus products and to any claims to royalties or other payments under that 1997 agreement. We paid TSRL total consideration of \$6,000,000, which is being amortized over 10 years under the straight-line method. Amortization expense for each of the three-month periods ended May 31, 2017 and 2016 was \$150,000 and was \$450,000 for each of the nine-month periods ended May 31, 2017 and 2016. Accumulated amortization as of May 31, 2017 and August 31, 2016 was \$1,825,000 and \$1,375,000, respectively.

Total amortization expense for intellectual property agreements for the three months ended May 31, 2017 and 2016 was \$151,875, and total amortization expense for the nine months ended May 31, 2017 and 2016 was \$455,625. Accumulated amortization as of May 31, 2017 was \$1,864,375 and \$1,408,750 as of August 31, 2016.

### Intangible assets

The Company acquired certain intangible assets as part of the acquisition of Cognigen Corporation on September 2, 2014. The following table summarizes those intangible assets as of May 31, 2017:

	Amortization Period	Acquisition Value	Accumulated Amortization	Net book value
Customer relationships	Straight line 8 years	\$1,100,000	\$ 378,125	\$721,875
Trade Name-Cognigen	None	500,000	–	500,000
Covenants not to compete	Straight line 5 years	50,000	27,500	22,500
		<b>\$1,650,000</b>	<b>\$ 405,625</b>	<b>\$1,244,375</b>

Amortization expense for each of the three-and nine-month periods ended May 31, 2017 and 2016 was \$36,875 and \$110,625, respectively. According to policy in addition to normal amortization, these assets are tested for impairment as needed.

### Earnings per Share

We report earnings per share in accordance with FASB ASC 260-10. Basic earnings per share is computed by dividing income available to common shareholders by the weighted-average number of common shares available. Diluted earnings per share is computed similar to basic earnings per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. The components of basic and diluted earnings per share for the three and nine months ended May 31, 2017 and 2016 were as follows:

	Three months ended		Nine months ended	
	5/31/2017	5/31/2016	5/31/2017	5/31/2016
Numerator:				
Net income attributable to common shareholders	\$2,080,029	\$1,909,339	\$4,637,354	\$4,161,161
Denominator:				
Weighted-average number of common shares outstanding during the period	17,241,891	17,028,634	17,233,470	17,000,228
Dilutive effect of stock options	343,637	198,906	221,394	219,607
	17,585,528	17,227,540	17,454,864	17,219,835

Common stock and common stock equivalents used for diluted earnings per share

Stock-Based Compensation

Compensation costs related to stock options are determined in accordance with FASB ASC 718-10, “*Compensation-Stock Compensation*”, using the modified prospective method. Under this method, compensation cost is calculated based on the grant-date fair value estimated in accordance with FASB ASC 718-10, amortized on a straight-line basis over the options’ vesting period. Stock-based compensation was \$142,879 and \$114,367 for the three months ended May 31, 2017 and 2016 respectively and \$355,365 and \$234,616 or the nine months ended May 31, 2017 and 2016, respectively. This expense is included in the condensed consolidated statements of operations as Selling, General, and Administration (SG&A), and Research and Development expense.

### Recently Issued Accounting Pronouncements

In May 2014, FASB issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers. The standard will eliminate the transaction- and industry-specific revenue recognition guidance under current 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). 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 early adopted ASU No. 2015-17 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. 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 that 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.

NOTE 3: Property and Equipment

Property and equipment as of May 31, 2017 consisted of the following:

Equipment	\$572,871
Computer equipment	230,229
Furniture and fixtures	127,857
Leasehold improvements	103,599
Sub total	1,034,556
Less: Accumulated depreciation and amortization	(777,004 )
Net Book Value	\$257,552

NOTE 4: CONTRACTS PAYABLE

TSRL

Pursuant to the termination and nonassertion agreement with TSRL (See note 2), the Company paid TSRL \$2,500,000 over a three-year period. The final payment of \$1,000,000 was made in April 2017.

NOTE 5: COMMITMENTS AND CONTINGENCIES

Employment Agreements

*CEO Employment Agreement*

In August 2014, we entered into an employment agreement with Mr. Woltosz for his services as our Chief Executive Officer, which was effective September 1, 2014 and continued until August 31, 2015 (the “September 2014 Agreement”). Under the terms of this employment agreement, Mr. Woltosz was required to devote a minimum of 60% of his productive time to performing the duties as our Chief Executive Officer. The agreement provided for an annual base salary of \$180,000, an annual performance bonus of up to 5% of the Company’s net income before taxes of the previous fiscal year, not to exceed \$36,000, and the grant of an option to purchase six shares of the Company’s common stock for each \$1,000 of net income before taxes that the Company earns at the end of each fiscal year (up to a maximum of 12,000 shares over the term of the agreement) with an exercise price equal to 10% over the market value per share as of the date of grant. In August 2015 this agreement was renewed for another year on the same terms. Under his current employment agreement, we agreed to provide Mr. Woltosz, at 60% of our actual costs, with such health insurance and other benefits which are appropriate to his office and position, adequate to the performance of his duties and not inconsistent with that which we customarily provide to our other management employees. We also agreed to reimburse him for customary, ordinary, and necessary business expenses incurred in connection with the rendering of services. The agreement also provides that we may terminate the agreement without cause upon thirty (30) days written notice, and that upon any such termination our only obligation to Mr. Woltosz would be for a payment equal to the greater of (i) 12 months of salary or (ii) the amount of salary for the remainder of the term of the agreement from the date of notice of termination. Further, the agreement provides that we may terminate the agreement for “cause” (as defined in the agreement) and that our only obligation to Mr. Woltosz upon any such termination would be limited to the payment of Mr. Woltosz’ salary and benefits through and until the effective date of any such termination. On July 9, 2015, the Company entered into a new employment agreement with Mr. Woltosz for another year on the same terms as the September 2014 agreement. A copy of this agreement was filed as an exhibit to the Current Form on Form 8-K filed with the Securities and Exchange Commission on July 15, 2015. On August 8, 2016 the Company entered into a new employment agreement for another year on the same terms as the September 2014 agreement. A copy of this agreement was filed as an exhibit to the Current Form on Form 8-K filed with the Securities and Exchange Commission on August 11, 2016.

*President’s employment agreement*

On September 2, 2014, Thaddeus H. Grasela, Jr., Ph.D., was appointed President of the Company and its wholly owned subsidiary Cognigen (also known as the Buffalo Division of the Company). The Company and Cognigen have entered into an Employment Agreement with Dr. Grasela (the “Grasela Employment Agreement”) that has a three-year term. Pursuant to the Grasela Employment Agreement, Dr. Grasela receives an annual base salary of \$250,000, is eligible to receive Company stock options under the 2007 Simulations Plus, Inc. Stock Option Plan, as determined by the Board, and is eligible to receive an annual performance bonus in an amount not to exceed 10% of salary to be determined by the Compensation Committee of the Board. The Compensation Committee awarded Dr. Grasela a \$25,000 performance bonus in each of September 2015 and September 2016 for the 2015 and 2016 fiscal years,

respectively.

### License Agreement

The Company executed a royalty agreement with Accelrys, Inc. (“Accelrys”) (the original agreement was entered into with Symyx Technologies in March 2010; Symyx Technologies later merged with Accelrys, Inc.) for access to their Metabolite Database for developing our Metabolite Module within ADMET Predictor™. The module was renamed the Metabolism Module when we released ADMET Predictor version 6 on April 19, 2012. Under this agreement, we pay a royalty of 25% of revenue derived from the sale of the Metabolism/Metabolite module to Accelrys. In 2014, Dassault Systemes of France acquired Accelrys and the Company now operates under the name BIOVIA. We incurred royalty expense of \$35,494 and \$44,485, respectively, and for the three months ended May 31, 2017 and 2016, respectively and \$108,587 and \$95,323 for the nine months ended May 31, 2017 and 2016, respectively.

### Income taxes

Our federal income tax returns for fiscal year 2012 thru 2015 are open for audit, and our state tax returns for fiscal year 2011 through 2015 remain open for audit. In addition our California tax return for the fiscal year 2007 and fiscal year 2008 remains open with regard to R&D tax credits as a result of a previous audit for which we received a letter from the California Franchise Tax Board stating that an audit will not be conducted for those years at this time; however it may be subject to future audit. In 2015 the Company was informed that the IRS was auditing the Company’s tax return for 2014. This audit was completed during FY2016; there were no changes as a result of the audit.

### Litigation

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

In June 2014, the Company was served with a complaint in a civil action entitled Sherri Winslow v. Incredible Adventures, Inc., et al. (Los Angeles Superior Court Case No. BC545789) alleging wrongful death and seeking unspecified damages arising out of a May 18, 2012 plane crash in the State of Nevada. The Company’s Chief Executive Officer owned the subject aircraft and is also a named defendant. The complaint alleged that the Company was the owner of the subject aircraft. The Company denied all material allegations against it, including that it owns or has ever owned any interest in the subject aircraft.

In June 2017, the Plaintiff settled the case with certain of the Defendants; the case was dismissed on June 20, 2017. The Company incurred no liability as part of the settlement and has been dismissed with prejudice.





## NOTE 6: SHAREHOLDERS' EQUITY

Dividend

The Company's Board of Directors declared cash dividends during fiscal years 2017 and 2016. The details of the dividends paid are in the following tables:

## FY2017

Record Date	Distribution Date	Number of Shares Outstanding on Record Date	Dividend per Share	Total Amount
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
<b>Total</b>				<b>\$2,585,043</b>

## FY2016

Record Date	Distribution Date	Number of Shares Outstanding on Record Date	Dividend per Share	Total Amount
11/09/2015	11/16/2015	16,996,001	\$0.05	\$849,800
1/29/2016	02/05/2016	17,018,001	\$0.05	\$850,900
5/02/2016	5/09/2016	17,029,051	\$0.05	\$851,475
8/11/2016	8/18/2016	17,221,978	\$0.05	\$861,099
<b>Total</b>				<b>\$3,413,274</b>

Stock Option Plan

In September 1996, the Board of Directors adopted, and the shareholders approved, the 1996 Stock Option Plan (the "Option Plan") under which a total of 1,000,000 shares of common stock had been reserved for issuance. In March 1999, the shareholders approved an increase in the number of shares that may be granted under the Option Plan to 2,000,000. In February 2000, the shareholders approved an increase in the number of shares that may be granted under the Option Plan to 4,000,000. In December 2000, the shareholders approved an increase in the number of shares that may be granted under the Option Plan to 5,000,000. Furthermore, in February 2005, the shareholders approved an additional 1,000,000 shares, resulting in the total number of shares that may be granted under the Option Plan to 6,000,000. The 1996 Stock Option Plan terminated in September 2006 by its term.

On February 23, 2007, the Board of Directors adopted, and the shareholders approved, the 2007 Stock Option Plan under which a total of 1,000,000 shares of common stock had been reserved for issuance. On February 25, 2014 the shareholders approved an additional 1,000,000 shares increasing the total number of shares that may be granted under the Option Plan to 2,000,000. This plan terminated in February 2017 by its term.

On December 23, 2016 the Board of Directors adopted, and on February 23, 2017 the shareholders approved, the 2017 Equity Incentive Plan under which a total of 1,000,000 shares of common stock has been reserved for issuance. This plan will terminate in December 2026.

Qualified Incentive Stock Options (Qualified ISO)

As of May 31, 2017 employees hold Qualified ISO to purchase 1,272,692 shares of common stock at exercise prices ranging from \$1.00 to \$10.06.

Transactions in FY17	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life
Outstanding, August 31, 2016	894,750	\$ 7.54	7.72
Granted	404,582	\$ 10.05	
Exercised	(9,892 )	\$ 7.00	
Cancelled/Forfeited	(16,748 )	\$ 9.24	
<b>Outstanding, May 31, 2017</b>	<b>1,272,692</b>	<b>\$ 8.32</b>	<b>7.82</b>
Exercisable, May 31, 2017	359,000	\$ 5.96	5.18

Non-Qualified Stock Options (Non-Qualified ISO)

As of May 31, 2017 the outside members of the Board of Directors and certain employees hold non-qualified options to purchase 47,168 shares of common stock at exercise prices ranging from \$4.46 to \$10.06.

Transactions in FY17	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life
Outstanding, August 31, 2016	52,750	\$ 6.88	8.07
Granted	17,418	\$ 10.05	
Exercised	(9,500 )	\$ 5.88	
Cancelled/Forfeited	(13,500)	\$ 7.43	
<b>Outstanding, May 31, 2017</b>	<b>47,168</b>	<b>\$ 8.10</b>	<b>8.61</b>
Exercisable, May 31, 2017	13,000	\$ 5.78	6.90

The weighted-average remaining contractual life of options outstanding issued under the Plan, both Qualified ISO and Non-Qualified SO, was 7.85 years at May 31, 2017. The exercise prices for the options outstanding at May 31, 2017 ranged from \$1.00 to \$10.06, and the information relating to these options is as follows:

Exercise Price		Awards Outstanding		Awards Exercisable			
Low	High	Quantity	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Quantity	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
\$1.00	\$1.50	67,000	1.85 years	\$ 1.00	67,000	1.85 years	\$ 1.00
\$3.01	\$4.50	20,000	1.10 years	\$ 3.16	20,000	1.10 years	\$ 3.16
\$4.51	\$6.00	70,000	1.66 years	\$ 5.52	70,000	1.66 years	\$ 5.52
\$6.01	\$7.50	341,040	7.28 years	\$ 6.86	136,620	7.30 years	\$ 6.86
\$7.51	\$9.00	10,000	9.25 years	\$ 8.62	—	—	\$ —
\$9.01	\$10.06	811,820	9.26 years	\$ 9.89	78,380	8.79 years	\$ 9.72
		<b>1,319,860</b>	<b>7.85 years</b>	<b>\$ 8.32</b>	<b>372,000</b>	<b>5.24 years</b>	<b>\$ 5.96</b>

## NOTE 7: RELATED PARTY TRANSACTIONS

As of May 31, 2017, included in bonus expenses to officers was \$45,750, of which \$27,000 was an accrued bonus representing an estimated amount of bonus payable to our Chief Executive Officer, Walter Woltoz as part of his current employment agreement, and \$18,750 accrued bonus representing an estimated amount of bonus payable to our President, Thaddeus Grasela as part of his current employment agreement.

May 1, 2017, Dr. Daniel Weiner was appointed as a member of the Board of Directors of the Company. Dr. Weiner also served on the Board of Directors of DILIsym. Immediately prior to the closing of the acquisition discussed in Subsequent Event Note 11, Dr. Weiner owned 5,000 shares of DILIsym's common stock (less than one percent of DILIsym's outstanding shares). At the closing of the Acquisition, Dr. Weiner received approximately \$29,000 in cash consideration of the sale of his shares of DILIsym to the Company and may receive up to an additional \$35,000 upon any payment of the holdback consideration and/or Earn-out Payments.

#### NOTE 8: CONCENTRATIONS AND UNCERTAINTIES

Revenue concentration shows that international sales accounted for 34% and 43.8% of net sales for the nine months ended May 31, 2017 and 2016, respectively. Three customers accounted for 8%, 6% (a dealer account in Japan representing various customers), and 5% of sales for the nine months ended May 31, 2017. Four customers accounted for 8% (a dealer account in Japan representing various customers), 6%, 5% and 5% of sales for the nine months ended May 31, 2016.

Accounts receivable concentrations shows that three customers comprised 14%, 12% (a dealer account in Japan representing various customers), and 8% of accounts receivable at May 31, 2017 compared to two customers comprising 15% and 11% (a dealer account in Japan representing various customers) at May 31, 2016.

We operate in the computer software industry, which is highly competitive and changes rapidly. Our operating results could be significantly affected by our ability to develop new products and find new distribution channels for new and existing products.

The majority of our customers are in the pharmaceutical industry. Consolidation and downsizing in the pharmaceutical industry could have an impact on our revenues and earnings going forward.

## NOTE 9: SEGMENT AND Geographic Reporting

We account for segments and geographic revenues in accordance with guidance issued by the FASB. Our reportable segments are strategic business units that offer different products and services.

Results for each segment and consolidated results are as follows for the three and nine months ended May 31, 2017 and 2016 (in thousands):

## Three months ended May 31, 2017

	Lancaster	Buffalo	Eliminations	Total
Net revenues	\$ 4,948	\$ 1,801		\$ 6,749
Income (loss) from operations	2,681	414		3,095
Identifiable assets	27,428	9,358	\$ (7,238 )	29,548
Capital expenditures	12	0		12
Capitalized software costs	278	66		344
Depreciation and amortization	422	92		514

## Three months ended May 31, 2016

	Lancaster	Buffalo	Eliminations	Total
Net Revenues	\$ 4,664	\$ 1,348		\$ 6,012
Income (loss) from operations	2,577	211		2,788
Total assets	26,532	9,504	\$ (7,238 )	28,798
Capital expenditures	3	27		30
Capitalized software costs	222	48		270
Depreciation and Amortization	381	98		479

## Nine months ended May 31, 2017

	Lancaster	Buffalo	Eliminations	Total
Net Revenues	\$ 12,685	\$ 5,187		\$ 17,872
Income (loss) from operations	5,739	1,079		6,818
Total assets	27,428	9,358	\$ (7,238 )	29,548
Capital expenditures	37	80		117
Capitalized software costs	809	120		929
Depreciation and Amortization	1,261	286		1,547

## Nine months ended May 31, 2016

Lancaster	Buffalo	Eliminations	Total
-----------	---------	--------------	-------

Edgar Filing: SIMULATIONS PLUS INC - Form 10-Q

Net Revenues	\$ 11,722	\$ 4,293		\$ 16,015
Income (loss) from operations	5,471	760		6,232
Total assets	26,532	9,504	\$ (7,238 )	28,798
Capital expenditures	4	28		32
Capitalized software costs	678	138		816
Depreciation and Amortization	1,171	279		1,450

In addition, the Company allocates revenues to geographic areas based on the locations of its customers. Geographical revenues for the three months and nine months ended May 31, 2017 and 2016 were as follows (in thousands):

Three months ended May 31, 2017

	North America	Europe	Asia	South America	Total
Lancaster	\$ 2,533	\$ 1,144	\$ 1,271	\$ 0	\$ 4,948
Buffalo	1,801	0	0	0	1,801
Total	\$ 4,334	\$ 1,144	\$ 1,271	\$ 0	\$ 6,749

Three months ended May 31, 2016

	North America	Europe	Asia	South America	Total
Lancaster	\$ 2,444	\$ 1,247	\$ 973	\$ 0	\$ 4,664
Buffalo	1,348	0	0	0	1,348
Total	\$ 3,792	\$ 1,247	\$ 973	\$ 0	\$ 6,012

## Nine months ended May 31, 2017

	North America	Europe	Asia	South America	Total
Lancaster	\$ 6,261	\$ 3,201	\$ 3,222	\$ 1	\$ 12,685
Buffalo	5,187	–	–	–	5,187
Total	\$ 11,448	\$ 3,201	\$ 3,222	\$ 1	\$ 17,872

## Nine months ended May 31, 2016

	North America	Europe	Asia	South America	Total
Lancaster	\$ 5,237	\$ 3,651	\$ 2,833	\$ 1	\$ 11,722
Buffalo	4,293	–	–	–	4,293
Total	\$ 9,530	\$ 3,651	\$ 2,833	\$ 1	\$ 16,015

## NOTE 10: EMPLOYEE BENEFIT PLAN

We maintain a 401(K) Plan for all eligible employees, and we make matching contributions equal to 100% of the employee's elective deferral, not to exceed 4% of total employee compensation. We can also elect to make a profit-sharing contribution. Our contributions to this Plan amounted to \$64,233 and \$61,028 for the three months ended May 31, 2017 and 2016 respectively and \$179,123 and \$168,654 for the nine months ended May 31, 2017 and 2016, respectively.

## NOTE 11: SUBSEQUENT EVENTS

On May 1, 2017, Simulations Plus, Inc. entered into a Stock Purchase Agreement (the "Agreement") with DILIsym Services, Inc., a North Carolina corporation ("DILIsym"), the shareholders of DILIsym (the "DILIsym Shareholders") and Brett A. Howell, the representative of the DILIsym Shareholders (the "DILIsym Shareholders Representative"), each, a "Party," and collectively, the "Parties."

On June 1, 2017, the Company consummated the acquisition of all outstanding capital stock of DILIsym pursuant to the terms of the Agreement and DILIsym became a wholly owned subsidiary of the Company (the "Acquisition"). Under the terms of the Agreement, the Company: (1) paid to the DILIsym Shareholders Five Million Dollars (\$5,000,000) payable at the closing of the Acquisition (the "Closing") subject to certain adjustments and holdbacks as provided in the Agreement and as more fully described below; and (2) will pay to the DILIsym Shareholders certain earn-out payments, to be measured by the adjusted earnings of DILIsym before income taxes, payable following the Closing, as more particularly described below and in the Agreement:

- a) On June 1, 2017, the Company paid the DILIsym Shareholders total cash consideration of \$4,515,982; which such amount included \$515,982 in working capital left in DILIsym's accounts in excess of the amount required under the Agreement,
  
- b) At the holdback release date, eighteen months from the Closing and subject to any offsets, the Company will pay \$1,000,000 of holdback consideration; and
  
- c) In addition, the Company may pay up to an additional \$5,000,000 in Earn-out Payments over the 3 years following the Closing if and when such Earn-out Payments become due and payable, and subject to certain offsets as provided in the Agreement, according to the Agreement.

The Company is currently in the process of preparing information for, and assessing the accounting treatment of the transaction.



## **Item 2. Management's Discussion and Analysis or Plan of Operations**

### **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,” “could,” “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 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.

### **General**

## BUSINESS

### 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, and is exploring the application of its machine-learning technologies in other industries, including aerospace/military and general healthcare. Our pharmaceutical/chemistry software is licensed to major pharmaceutical, biotechnology, agrochemical, and food industry companies and to regulatory agencies worldwide for use in the conduct of industry-based research. We also provide consulting services ranging from early drug discovery through preclinical and clinical trial data analysis and for submissions to regulatory agencies. As the result of acquiring our Cognigen division in Buffalo in 2014, we are 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. In addition, we have 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. Simulations Plus is headquartered in Southern California, with additional offices in Buffalo, New York; San Diego, California; Auburn, Alabama; Guerneville, California; and Raleigh-Durham, North Carolina. The Company's 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 preclinical and clinical consulting services and software from early discovery all the way through clinical trials and beyond to post-patent support of generic drug companies. 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 physiologically based pharmacokinetics (PBPK) modeling and simulation and for prediction of molecular properties from structure.

We generate revenue by delivering relevant, cost-effective software and creative and insightful consulting services. Pharmaceutical and biotechnology companies use our software programs and scientific knowledge to guide early drug discovery (molecule design and screening), preclinical development, clinical development, and generic product development programs. They 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, optimize clinical trial design, and simulate outcomes in special populations, such as the elderly and pediatric patients.

## PRODUCTS

### General

We currently offer eight software products for pharmaceutical research and development: three simulation programs that provide time-dependent results based on solving large sets of differential equations: GastroPlus™; DDDPlus™; and MembranePlus™; 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™); our newest program which is designed for rapid clinical trial data analysis and regulatory submissions called PKPlus™; and one 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, and currently our largest source of revenue, is GastroPlus. GastroPlus simulates the absorption, pharmacokinetics, and pharmacodynamics of drugs 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. The FDA currently has 70 GastroPlus licenses.

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, begun in 2012, is an international collaboration among 27 industry, academic, and government organizations working in the area of oral absorption of pharmaceutical products. Because we are outside of the European Union, our participation in this project has been at our own expense, while other members are compensated for their work; however, we are a full member with access to all of the data and discussions of all other members. We believe our investment to participate in this initiative has enabled us to benefit from, and to contribute to, advancing the prediction of human oral bioavailability from preclinical data, and ensures that we are well-known to member pharmaceutical companies and regulatory agencies.

In September 2016 we announced that Simulations Plus had been invited to join the European SimInhale Consortium and had been admitted to this prestigious group focused on advancing the state of the art for simulation of inhaled dosage forms. As one of only two U.S. participants, Simulations Plus is participating in activities designed to advance particle designs for improved deposition and interaction with lung tissue; promote realistic computer simulations of particle aerosolization, delivery, and deposition; promote patient-tailored inhaled medicines; promote integration of device and formulation design; and promote critical assessment of toxicity issues and related risks.

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 is to provide a tool for generic companies and the FDA to assess the likely bioequivalence of generic drug formulations dosed to the eye. Under this RCA, we receive up to \$200,000 per year. This RCA may be renewed for up to a total of three years based on the progress achieved during the project. After a successful second year, the RCA was renewed for its third year in September 2016, and will expire in September 2017.

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. This type of dosage form is usually injected via subcutaneous or intramuscular routes, but can also be used for ocular dosing. Once again, this RCA 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 first year, the RCA was renewed for the second year in September 2016, and will expire in September 2017 unless further renewed.

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 April 2017, we released Version 9.5 of GastroPlus after nearly two years of improvements over version 9.0, which was released in April 2015. Version 9.5 is now the largest single upgrade we've made to the program. 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:

- ability to simulate the absorption and distribution of antibody-drug conjugates (ADCs), which are antibodies that are used to carry small drug molecules to the intended target tissue
- ability to dose via intramuscular injection and an improved model for subcutaneous injection
- several new physiology models, including Chinese and hepatic impairment populations
- revamped workflows for building *in vitro-in vivo* correlations (IVIVCs) and performing virtual bioequivalence trial simulations
- improved reporting capabilities, making it easier for companies wishing to submit results to regulatory agencies

Our goal with GastroPlus is to integrate the most advanced science into user-friendly software to enable pharmaceutical researchers and regulators to perform sophisticated analyses of complex drug 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 further penetrate the biopharmaceuticals, food, cosmetics, and general toxicology markets.

#### DDDPlus

DDDPlus simulates *in vitro* (laboratory) experiments that measure the rate of dissolution of a drug and, 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, and (3) design *in vitro* dissolution experiments to better mimic *in vivo* (animal and human) conditions. 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.

#### MembranePlus™

MembranePlus was released in October 2014. Similar to DDDPlus, MembranePlus simulates laboratory experiments, but in this case, the experiments are for measuring permeability of drug-like molecules through various membranes, including several different 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.

#### PKPlus™

On August 25, 2016, we announced the release of a new 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 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 new standalone PKPlus program has been

developed to provide 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 NCA and compartmental PK modeling. After receiving considerable feedback on version 1.0, we are modifying the program to include a number of additional features requested by our users and potential users and expect to release the next version later this year. We believe the potential number of eventual users for PKPlus is in the thousands world-wide and that it has the potential to eventually become one of our leading revenue producers.

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 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.

For many years, ADMET Predictor has been top-ranked for predictive accuracy in multiple peer-reviewed, independent comparison studies, while generating its results at a high throughput rate. Although the state of the art of this type of software does not enable identifying the best molecule in a series, it does allow early screening of molecules that are highly likely to fail as potential drug candidates (i.e., the worst molecules, which is usually the majority of a chemical library) before synthesizing and testing them. Thus, millions of 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 most recent release of ADMET Predictor, version 8.0, was released on August 1, 2016. This new version features a completely redesigned and modernized interface as well as a number of new capabilities to enhance the performance and user-friendliness of the program. In addition, we have integrated a number of MedChem Studio features into the new ADMET Predictor, and created a tighter integration between the two programs when a MedChem Studio license is obtained along with an ADMET Predictor license.

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 machine-learning methods we use to build our top-ranked property predictions. Pharmaceutical companies expend substantial time and money conducting a wide variety of experiments on new molecules each year, 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 models with minimal training.

We released version 8.1 in January 2017. This new release includes:

- 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
- Model-building in ADMET Modeler has been streamlined and made much more efficient
- The MedChem Studio™ Module includes combinatorial substituent and scaffold replacement operations
- New *in silico* Ames tests have been added to produce reliable confidence predictions and are more broadly applicable
- ADMET Risk™ scores are now accessible graphically in histograms

Version 8.5 is now well along in development and will add a number of powerful new features, including significant improvements to the ADMET Modeler Module.

#### Potential new markets for machine learning

We are currently investigating applications of our sophisticated machine-learning engine outside of our normal pharmaceutical markets. To date, we have conducted several proof-of-concept studies including: (1) building predictive models for 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 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 launched in 2011. It was initially a molecule-drawing program, or “sketcher”, but now has capabilities exceeding those of other molecule-drawing programs because of its integration with both MedChem Studio and ADMET Predictor. We provide MedChem Designer for free because we believe that in the long run it will help to increase demand for ADMET Predictor and MedChem Studio, and because most other existing molecule-drawing programs are also 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 18,000 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 5 or 6), 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 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 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. MedChem Studio version 4.0 was released during fiscal year 2014. We have now merged MedChem Studio with the refactoring of ADMET Predictor 8.0, 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 combined COX-1 and COX-2 inhibitors. 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.

### 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 provides our user community with access to new features that accelerate completion of modeling projects by decreasing run times and facilitating the comparison and exporting of results across models. These features include 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 new 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 can now conveniently copy visualization preferences across projects, improving consistency and facilitating collaboration and communication with clients and colleagues. We are now further enhancing KIWI as part of our five-year, almost-\$5 million contract with a leading global research foundation.

### **Contract Research and Consulting Services**

Our scientists and engineers have expertise in drug absorption via various dosing routes (oral, intravenous, ocular, nasal/pulmonary, and dermal), pharmacokinetics, and pharmacodynamics. They have attended over 200 scientific meetings worldwide in the past four years, often speaking and presenting. We frequently conduct contracted consulting studies for large customers (including the five largest 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.

We continue working on a five-year consulting agreement with a major research foundation to implement a platform for coordinating the data generated by global teams engaged in model-based drug development.

We currently are working with the FDA on three different Research Collaboration Agreements (RCAs): two funded efforts for the ocular model and long-acting injectable microspheres and the unfunded IVIVC effort, all described above under “GastroPlus”. We also successfully completed the fifth year of our five-year renewable collaboration with the Center for Food Safety and Nutrition of the FDA to develop predictive toxicity models for food additives and contaminants.

### **Pharmacometric Modeling**

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 30-40 drug projects per year. The model-based analysis of clinical trial data that we perform is different from the modeling analysis offered by GastroPlus; the former relies more on statistical and semi-mechanistic models, whereas the latter relies 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 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.

### **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 BIOVIA, a San Diego division of Dassault Systemes in France (formerly known as Accelrys, Inc.), pursuant to which a small royalty is paid to BIOVIA from revenues on each license for the Metabolite module in ADMET Predictor. This license agreement continues in perpetuity and either party has the right to terminate it.

In 1997 we entered into an exclusive software licensing agreement with TSRL, Inc. (aka Therapeutic Systems Research Laboratories) (TSRL), 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 have now been made as of April 2017. Our payment obligation 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 \$900,000 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, 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 50 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 one independent distributor in Japan and two independent representatives in China 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 group following the example set in Japan. Over 850 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, and New York, with California locations in Lancaster, Gureneville, San Jose, and San Diego, and in Buffalo, New York. In addition, our Chief Executive Officer works primarily from Auburn, Alabama. 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 management believes there is currently no significant competitive threat to GastroPlus; however, in spite of a high barrier to entry, one could be developed over time. Our new PKPlus software product will compete with one major and a few minor software programs; however, the capabilities and design features of PKPlus, along with more affordable licensing, are expected to generate significant interest. MedChem Studio, MedChem Designer, and ADMET Predictor/ADMET Modeler operate in a more competitive environment. Several other companies presently offer simulation or modeling software, or simulation-software-based services, to the pharmaceutical industry.

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

larger pharmaceutical companies.

Although competitive products exist, both new licenses and license renewals for GastroPlus have continued to grow. 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, and KIWI 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) attract and retain a highly skilled scientific and engineering team, (5) aggressively 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 and to explore opportunities in aerospace and general healthcare.

## **STRATEGY**

Our business strategy is to do the things we need to do to promote growth both organically (i.e., by expanding our current products and services through in-house efforts) and by acquisition. We believe in the “Built to Last” approach - that the fundamental science and technologies that underlie our business units are the keys both to improving our existing products and to expanding the product line with new products that meet our various customers’ needs. We believe the continued growth of our pharmaceutical software and services business segment is the result of steadily increasing adoption of simulation and modeling software tools across the pharmaceutical industry, as well as the world-class expertise we offer as consultants to assist companies involved in the research and development of new medicines. We have received a continuing series of study contracts with pharmaceutical companies ranging from several of the largest in the world to a number of medium-sized and smaller companies in the U.S. and Europe.

In the fiscal year ended August 31, 2016 we distributed \$0.20 per share in dividends to our shareholders. In November 2016, February 2017, and May 2017 we distributed quarterly dividends of \$0.05 per share. We anticipate future dividends to be at least \$0.05 per share per quarter; however, there can be no assurances that such dividends will be distributed, or if so, whether the amounts will be more, less, or the same as expected. The Board of Directors must approve each quarterly dividend distribution and may decide to increase, decrease, or eliminate dividend distributions at any time.

## Results of Operations

### *Comparison of Three Months Ended May 31, 2017 and 2016.*

The following table sets forth our condensed statements of operations (in thousands) and the percentages that such items bear to net sales (because of rounding, numbers may not foot):

	Three Months Ended			
	5/31/17		5/31/16	
Net revenues	\$6,749	100.0%	\$6,012	100.0%
Cost of revenues	1,445	21.4	1,195	19.9
Gross profit	5,304	78.6	4,817	80.1
Selling, general and administrative	1,955	29.0	1,681	28.0
Research and development	254	3.7	348	5.8
Total operating expenses	2,209	32.7	2,029	33.8
Income from operations	3,095	45.9	2,788	46.4
Other income	(10 )	(0.2 )	12	0.2
Income from operations before taxes	3,085	45.7	2,800	46.6
(Provision for) income taxes	(1,005)	(14.9 )	(891 )	(14.8 )
Net income	\$2,080	30.8%	\$1,909	31.8%

### Net Revenues

Consolidated net revenues increased by 12.2% or \$736,000 to \$6.75 million in the third fiscal quarter of Fiscal Year 2017 (“3QFY17”) from \$6.01 million in the third fiscal quarter of Fiscal Year 2016 (“3QFY16”). This net increase was due to a \$284,000 increase in revenues generated by our Lancaster Division, representing a 6.1% increase over 3QFY16, along with an increase of \$453,000 or 33.6% in revenues of our Buffalo Division to \$1.80 million in 3QFY17 from \$1.35 million in 3QFY16. Consolidated software and software-related sales increased \$223,000 or 4.9%, while consolidated consulting and analytical study revenues increased \$513,000 or 34.9% over 3QFY16.

Cost of Revenues

Consolidated cost of revenues increased by \$250,000, or 20.9%, in 3QFY17 to \$1.45 million from \$1.20 million in 3QFY16. Cost of Revenues as a percentage of revenue increased by 1.5% in 3QFY17 to 21.4% as compared to 19.9% in 3QFY16. \$209,000 of the increased costs are allocated labor related to increased studies and contracts, and software amortization increase by \$50,000.

Gross Profit

Consolidated gross profits increased \$486,000 or 10.1%, to \$5.30 million in 3QFY17 from \$4.82 million in 3QFY16. Our Lancaster Division accounted for a \$233,000 increase, which came from a mix of increased software license sales and analytical study revenues, while our Buffalo Division showed a \$253,000 increase mainly from consulting revenues. Consolidated Gross profit as a percentage of revenues decreased 1.5% to 78.6% in 3QFY17 from 80.1% in 3QFY16.

Selling, General and Administrative Expenses

Selling, general, and administrative (SG&A) expenses increased \$274,000, or 16.3%, to \$1.95 million in 3QFY17, from \$1.68 million in 3QFY16.

The major increases in SG&A expenses this year compared to last year were:

- Commissions increased \$94,000 – higher commissionable sales in Asia
- Salaries and Wages increased \$94,000 – increases in wages over the prior year, higher increased non-cash stock compensation costs, and a higher percentage of allocated G&A labor by scientific staff.
- Recruitment and Hiring increased \$34,000 – hiring fees and moving costs for increased staffing
- Acquisition Costs DILIsym Services, Inc.—costs of acquisition during the quarter were \$144,000 which included legal, M&A, accounting and other direct acquisition related costs

The major decreases in SG&A expenses this year compared to last year were:

- Selling expenses decreased by \$27,000 web and website redevelopment costs were down over the prior year
- Professional Fees-Accounting—decreased by \$55,000 lower compliance cost associated with Sarbanes-Oxley incurred in the current year





Research and Development

Total research and development cost decreased \$19,000 in 3QFY17 compared to 3QFY16. In 3QFY17 we incurred approximately \$598,000 of research and development costs, of which \$344,000 was capitalized and \$254,000 was expensed. In 3QFY16 we incurred approximately \$617,000 of research and development costs, of which \$269,000 was capitalized and \$348,000 was expensed.

Provision for Income Taxes

The provision for income taxes was \$1.00 million for 3QFY17 compared to \$891,000 for 3QFY16. Our effective tax rate decreased to 32.57% in 3Q17 from 34.4% in 3QFY16. This decrease is a result of the effect of tax credits and equity based compensation on earnings in 3QFY17.

Net Income

Net income increased by \$171,000 or 8.9%, in 3QFY17 to \$2.08 million from \$1.91 million in 3QFY16. Net earnings from our Lancaster division were up \$36,000 or 2.0% to \$1.78 million in 3QFY17. Approximately \$144,000 in one-time pretax charges related to the acquisition of DILIsym Services, Inc. were expensed to the Lancaster division in this reporting period, which lowered net income by approximately \$97,000 for 3QFY17. Net earnings for our Buffalo division increased by \$131,000 or 102.3% to \$266,000 in 3QFY17.

***Comparison of Nine Months Ended May 31, 2017 and 2016***

The following table sets forth our condensed statements of operations (in thousands) and the percentages that such items bear to net sales (because of rounding, numbers may not foot):

	Nine Months Ended			
	5/31/17		5/31/16	
Net revenues	\$17,872	100.0%	\$16,015	100.0%
Cost of revenues	4,335	24.2	3,542	22.1
Gross profit	13,537	75.8	12,473	77.9
Selling, general and administrative	5,767	32.3	5,080	31.7
Research and development	953	5.3	1,161	7.3
Total operating expenses	6,719	37.6	6,241	39.0
Income from operations	6,818	38.2	6,232	38.9
Other income	19	0.1	(22 )	(0.1 )
Income from operations before taxes	6,837	38.3	6,210	38.8

Edgar Filing: SIMULATIONS PLUS INC - Form 10-Q

(Provision for) income taxes	(2,200 )	(12.3 )	(2,048 )	(12.8 )
Net income	\$4,637	25.9%	\$4,161	26.0%

Net Revenues

Consolidated net revenues increased by 11.6% or \$1.86 million to \$17.87 million in the first nine months of Fiscal Year 2017 (“9moFY17”) from \$16.01 million in the first nine months of Fiscal Year 2016 (“9moFY16”). \$895,000 of this increase was from revenues generated by our Buffalo Division, representing a 20.8% increase over 9moFY16. Net revenues of the Lancaster Division increased \$963,000, or 8.2%, to \$11.72 million for 9moFY17 from \$11.72 million in 9moFY16. Consolidated software and software-related sales increased \$751,000, or 6.7%, in 9moFY17, while consolidated consulting and analytical study revenues increased \$1.11 million, or 23.2%, over 9moFY16.

Cost of Revenues

Consolidated cost of revenues increased by 22.4% or \$793,000 in 9moFY17 to \$4.33 million from \$3.54 million in 9moFY16. The increase came mainly from \$472,000 of increased labor related to studies and contracts, \$65,000 of increased costs associated with training programs, increased software amortization of \$129,000, and \$108,000 of direct contract-related expenses. Consolidated cost of revenues as a percentage of revenue increased from 22.1% in 9moFY16 to 24.2% in 9moFY17.

Gross Profit

Consolidated gross profit increased \$1.06 million or 8.5%, to \$13.53 million in 9moFY17 from \$12.47 million in 9moFY16. \$415,000 of this increase in gross margin is from our Buffalo Division, which showed a 56.9% gross margin on \$5.19 million in revenues for 9moFY17. Our Lancaster Division accounted for \$649,000 of the increase, showing an 83.4% gross margin for the nine-month period.

Selling, General and Administrative Expenses

Selling, general, and administrative (SG&A) expenses increased \$687,000 or 13.5%, to \$5.77 million in 9moFY17 from \$5.08 million in 9moFY16.

- Salaries and Wages increased \$183,000 – increases in wages, taxes, and benefits over the prior year, higher annual bonuses paid based on increased profit, increased non-cash stock compensation costs, and a higher percentage of allocated G&A labor by scientific staff
- Commission expense increased \$102,000 – higher commissionable sales in Asia
- Professional fees increased \$316,000 – this increase is the result of the company’s transition to accelerated filer status and the cost of the Company’s Sarbanes-Oxley internal-control-related costs, as well as additional accounting compliance and legal costs associated with reviews of our proxy, 10-K, Equity Incentive Plan, and other corporate documents
- Acquisition Costs DILIsym Services, Inc.—costs of acquisition during the nine months were \$261,000, which included legal, M&A, accounting and other direct acquisition related costs

The major decreases in SG&A expenses this year compared to last year were:

- Selling expenses decreased by \$53,000 mostly as advertising and website redevelopment costs were down over the prior year
- Travel and Entertainment decreased by \$45,000 – lower cost of conference attendance and foreign travel

Research and Development

We incurred approximately \$1.89 million of research and development costs during 9moFY17. Of this amount, \$928,000 was capitalized software development costs and \$952,000 was expensed. We incurred approximately \$1.97 million of research and development costs during 9moFY16. Of this amount, \$814,000 was capitalized software development costs and \$1.16 million was expensed.

Other income (expense)

Other income increased \$41,000 in 9moFY17 and showed income of \$19,000 in 9moFY17 compared to an expense of \$21,000 in 9MoFY16. Foreign currency exchange gains accounted for this change due to the dollar strengthening in relation to the Japanese yen.

Provision for Income Taxes

The provision for income taxes was \$2.20 million for 9moFY17 compared to \$2.05 million for 9moFY16. Our effective tax rate decreased to 32.2% in 9moFY17, down from 33.0% in 9moFY16 due mainly to the effect of stock-based compensation.

### Net Income

Net income increased by \$476,000, or 11.4%, to \$4.64 million in 9moFY17 from \$4.16 million in 9moFY16. The increase comes from revenue growth in both divisions of the Company. Net earnings from our Lancaster division were up \$260,000 or 7% to \$3.95 million in 9moFY17 from \$3.69 million in 9moFY16. Approximately \$261,000 in one-time pretax charges related to the acquisition of DILIsym Services, Inc. were expensed to the Lancaster division in 9moFY17, which lowered net income by approximately \$177,000. Net earnings for our Buffalo division increased by \$216,000 or 45.9% to \$687,000 in 9moFY17 from \$471,000 in 9moFY16.

### **Liquidity and Capital Resources**

Our principal sources of capital have been cash flows from our operations. We have achieved continuous positive operating cash flow over the last nine 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 expanded 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. If cash flows from operations became insufficient to continue operations at the current level, and if no additional financing was obtained, then management would restructure the Company in a way to preserve its pharmaceutical business while maintaining expenses within operating cash flows.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

As of May 31, 2017 and August 31, 2016, we had cash and cash equivalents of \$8.25 million and \$8.03 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 three months and nine months ended May 31, 2017 and 2016 we sold \$795,000 and \$466,000, and \$1.77 million and \$1.73 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 4. Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of May 31, 2017. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, management concluded as of May 31, 2017, that our disclosure controls and procedures were effective.

#### ***Changes in Internal Control over Financial Reporting***

During the quarter ended May 31, 2017 we had implemented additional measures to remediate the underlying causes of the material weaknesses related to Information Technology General Controls identified in our annual report for the year ended August 31, 2016, including enhancing our internal documentation and monitoring approach to ensure that all GITC procedures designed to restrict access to applications and data are operating in an optimal manner in order to provide management with comfort that access is properly limited to the appropriate internal personnel.

Our management, including our CEO, president, and CFO, do not expect that our disclosure controls or internal controls over financial reporting will prevent all errors or all instances of 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. Further, 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. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and any design may not succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitation of a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

## **Part II. Other Information**

### **Item 1. Legal Proceedings**

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

In June 2014, the Company was served with a complaint in a civil action entitled Sherri Winslow v. Incredible Adventures, Inc., et al. (Los Angeles Superior Court Case No. BC545789) alleging wrongful death and seeking unspecified damages arising out of a May 18, 2012 plane crash in the State of Nevada. The Company's Chief Executive Officer owns the subject aircraft and is also a named defendant. The complaint alleged that the Company was the owner of the subject aircraft. The Company denied all material allegations against it, including that it owns or has ever owned any interest in the subject aircraft.



In June 2017 the Plaintiff settled the case with certain of the Defendants; the case was dismissed on June 20, 2017. The Company incurred no liability as part of the settlement and has been dismissed with prejudice.

## **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 Quarterly Report on Form 10-Q, 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.*

### **Risks Relating to the Pending Transactions**

**None pending**

### **Certain Risks Related to Our Marketplace and Environment**

- a) ***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, agritech, 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 2014, 2015, and 2016, 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, and Buffalo, New York. 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 i) 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 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 failure on our part to comply with applicable regulations could result in the termination of ongoing research or the j) 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 k) 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 l) 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.

m) ***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, 2016, the carrying amount of goodwill and other intangibles was \$6,144,248 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 *a)* 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 **b)** 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, 2016, 2015 and 2014, 38%, 37% and 48% 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 **c)** 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 **d)** 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.

f)

g) **Contract research services create a risk of liability.** As a CRO, we face a range of potential liabilities which may include:

1. 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

2. 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).

h) **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.

i) **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  
j) 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, 2016, we had no borrowed debt and have no need to do so to fund normal operations in the foreseeable future; however, should  
k) circumstance 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. Walter S. Woltosz, our Chief Executive Officer and Chairman of the Board, has held his position since our the founding in 1996. We have an annual employment agreement with Mr. Woltosz. Our President, Thaddeus “Ted” Grasela, has an employment contract that expires in August 2017. No other members of our senior management and scientific personnel are under contract. If  
l) Mr. Woltosz, Dr. Grasela, 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.*** In September 2014, the Company expanded our business through an acquisition. We to 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 m) 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.*** n) 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:

- a. changes in the general global economy;
- b. the number and scope of ongoing client engagements; the commencement, postponement, delay, progress, completion, or cancellation of client contracts in the quarter;
- c. changes in customer budget cycles;
- d. the number and scope of ongoing client engagements;
- e. the commencement, postponement, delay, progress, completion, or cancellation of client contracts in the quarter;
- f. changes in the mix of our products and services;

- g. competitive pricing pressures;
- h. the extent of cost overruns;
- i. buying patterns of our clients;
- j. budget cycles of our clients;
- k. the effect of potential acquisitions and consequent integration;
- l. the timing of new product releases by us or our competitors;
- m. 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;
- n. changes in tax laws, rules, regulations, and tax rates in the locations in which we operate;
- o. the timing and charges associated with completed acquisitions and other events;
- p. the financial performance of the limited partnerships in which we invest; and
- q. 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.*** Three customers accounted for 10% (a dealer account in Japan representing various customers), 7% and 6% of net sales for fiscal year 2016. Three customers accounted for 10% (a dealer account in Japan representing various customers), 8% and 6% of net sales for fiscal year 2015. Two customers accounted for 14% (actually a dealer account in Japan representing various customers), and 8% of net sales for fiscal year 2014.

***o) 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

***p) 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

***q) 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.***

***r) 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 t) 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 u) 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 v) 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.

***aa) 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 NASDAQ Stock Market, we must comply with various laws, regulations and requirements. New laws and regulations, as ***bb)*** 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 Stock 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.*

*cc)* 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 *dd)* traded as high as \$13.00 and as low as \$0.38 from our IPO through May 31, 2017. However, an active, liquid, and orderly market for our common stock on The NASDAQ Stock 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:

- a.* our quarterly or annual earnings or those of other companies in our industry;
- b.* announcements by us or our competitors of significant contracts or acquisitions;
- c.* changes in accounting standards, policies, guidance, interpretations, or principles;
- d.* general economic and stock market conditions, including disruptions in the world credit and equity markets;
- e.* the failure of securities analysts to cover our common stock or changes in financial estimates by analysts;
- f.* future sales of our common stock; and
- g.* 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 2. Changes in Securities**

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

N/A

**Item 5. Other Information**

N/A

**Item 6. Exhibits**

EXHIBIT NUMBER	DESCRIPTION
2.1	Agreement and Plan of Merger, dated July 23, 2014, by and among the Company, Cognigen Corporation and the other parties thereto. (13)^
3.1	Articles of Incorporation of the Company. (5)
3.2	Amended and Restated Bylaws of the Company. (5)
4.1	Articles of Incorporation of the Company. (incorporated by reference to Exhibit 3.1 hereof)
4.2	Amended and Restated Bylaws of the Company. (incorporated by reference to Exhibit 3.2 hereof)
4.3	Form of Common Stock Certificate (1)
4.4	Share Exchange Agreement (1)
10.1	The Company's 1996 Stock Option Plan and forms of agreements relating thereto (1) (†)
10.2(a)	Exclusive License Software Agreement by and between the Company and Therapeutic Systems Research Laboratories dated June 30, 1997. (2)

- 10.2(b) Termination and Non-Assertion Agreement entered into on May 15, 2014 by and between the Company and TSRL, Inc. (11)
- 10.3(a) The Company's 2007 Stock Option Plan. (3) (†)
- 10.3(b) The Company's 2007 Stock Option Plan as amended as of December 6, 2013. (10) (†)
- 10.4(a) Lease dated May 12, 2005 by and between Freeway Ventures, LLC and the Company. (6)
- 10.4(b) Notice of Election to Extend Term of Lease by and between the Company and Crest Development LLC (formerly Freeway Ventures LLC) dated July 29, 2010.(4)
- 10.4(c) One Amendment to Lease by and between the Company and Crest Development LLC entered into as of May 23, 2013. (8)
- 10.4(d) Second Amendment to Lease by and between the Company and Crest Development LLC Entered into as of May 1 2016
- 10.5 Stock Purchase Agreement by and among the Company, Words+, Inc., and Prentke Romich Company dated November 15, 2011. (7)
- 10.6 Employment Agreement by and between the Company and Walter S. Woltosz, dated as of July 22, 2011. (5) (†)
- 10.7 Employment Agreement by and between the Company and Walter S. Woltosz, dated as of August 22, 2013. (9) (†)
- 10.8 Employment Agreement by and between the Company and Walter S. Woltosz, dated as of August 28, 2014. (12) (†)
- 10.9 Employment Agreement by and between the Company and Thaddeus H Grasela Jr. dated as of September 2, 2014. (12) (†)
- 10.10 Employment Agreement by and between the Company and Walter S. Woltosz, dated as of July 9, 2015. (9) (†)
- 10.11 Employment Agreement by and between the Company and Walter S. Woltosz, dated as of August 8, 2016. (9) (†)
- 10.12 2017 Equity Incentive Plan
- 10.13 Stock Purchase Agreement by and among Simulation Plus, Inc., DILIsym Services, Inc., The Shareholders' Representative and The Shareholders of DILIsym Services, Inc\*\*
- 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.

^ 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.

† Those exhibits marked with a (†) refer to management contracts or compensatory plans or arrangements

\* Filed herewith

\*\* Furnished herewith

Edgar Filing: SIMULATIONS PLUS INC - Form 10-Q

- (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 the Company's Form 10-KSB for the fiscal year ended August 31, 1997.
- (3) Incorporated by reference to the Company's Form 10-K for the fiscal year ended August 31, 2009.
- (4) Incorporated by reference to the Company's Form 10-K for the fiscal year ended August 31, 2010.
- (5) Incorporated by reference to the Company's Form 10-K for the fiscal year ended August 31, 2011.
- (6) Incorporated by reference to the Company's Form 10-KSB for the fiscal year ended August 31, 2006.
- (7) Incorporated by reference to the Company's Form 8-K filed November 16, 2011.
- (8) Incorporated by reference to the Company's Form 10-Q filed July 10, 2013.
- (9) Incorporated by reference to the Company's Form 10-K filed November 18, 2013.
- (10) Incorporated by reference to the Company's Form 10-Q filed April 9, 2014.
- (11) Incorporated by reference to the Company's Form 8-K filed May 19, 2014.
- (12) Incorporated by reference to the Company's Form 8-K filed September 4, 2014.
- (13) Incorporated by reference to the Company's Form 8-K/A filed November 18, 2014.
- (14) Incorporated by reference to the Company's Form 8-K filed July 15, 2015.

**SIGNATURES**

In accordance with Section 13 or 15 (d) of the Securities Exchange Act of 1934, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Lancaster, State of California, on July 10, 2017.

Simulations Plus, Inc.

Date: July 10, 2017 By: /s/ John R Kneisel

John R. Kneisel

Chief Financial Officer