

SIMULATIONS PLUS INC  
Form 10-Q  
July 14, 2016

**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, 2016**

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

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 14, 2016 was 17,051,964; no shares of preferred stock were outstanding.

**Simulations Plus, Inc.**

**FORM 10-Q**

**For the Quarterly Period Ended May 31, 2016**

Table of Contents

**PART I. FINANCIAL INFORMATION**

	<u>Page</u>
Item 1. Condensed Financial Statements	
Condensed Consolidated Balance Sheets at May 31, 2016 (unaudited) and August 31, 2015 (audited)	3
Condensed Consolidated Statements of Operations for the three months and nine months ended May 31, 2016 and 2015 (unaudited)	4
Condensed Consolidated Statements of Cash Flows for the nine months ended May 31, 2016 and 2015 (unaudited)	5
Notes to Condensed Consolidated Financial Statements (unaudited)	6
Item 2. Management’s Discussion and Analysis of Financial Condition and Result of Operations	17
General	17
Result of Operations	24
Liquidity and Capital Resources	27
Item 3. Quantitative and Qualitative Disclosures about Market Risk	27
Item 4. Controls and Procedures	27

**PART II. OTHER INFORMATION**

Item 1. Legal Proceedings	29
Item 1A. Risk Factors	29
Item 2. Changes in Securities	29
Item 3. Defaults upon Senior Securities	29

Item 4. Mine Safety Disclosures	29
Item 5. Other Information	29
Item 6. Exhibits	30
Signature	31

**SIMULATIONS PLUS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****As of**

	(Unaudited) May 31,	(Audited) August 31,
	2016	2015
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$7,279,683	\$8,551,275
Accounts receivable, net of allowance for doubtful accounts of \$0	4,582,573	1,593,707
Revenues in excess of billings	1,039,897	795,125
Prepaid income taxes	108,690	–
Prepaid expenses and other current assets	288,164	381,718
Deferred income taxes	289,835	210,972
Total current assets	13,588,842	11,532,797
Long-term assets		
Capitalized computer software development costs, net of accumulated amortization of \$8,368,000 and \$7,632,421	3,878,342	3,798,339
Property and equipment, net (note 3)	297,385	413,510
Intellectual property, net of accumulated amortization of \$1,256,875 and \$801,250	4,818,125	5,273,750
Other intangible assets net of accumulated amortization of \$258,125 and \$147,500	1,391,875	1,502,500
Goodwill	4,789,248	4,789,248
Other assets	34,082	34,082
Total assets	\$28,797,899	\$27,344,226
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$184,996	\$209,407
Accrued payroll and other expenses	510,792	429,580
Accrued bonuses to officers	90,750	121,000
Income taxes payable	–	43,602
Other current liabilities	13,239	19,859
Current portion - Contracts payable (note 4)	2,854,404	2,604,404
Billings in excess of revenues	112,445	106,534
Deferred revenue	261,266	78,945
Total current liabilities	4,027,892	3,613,331
Long-term liabilities		
Deferred income taxes	3,264,372	3,190,419
Payments due under Contracts payable (note 4)	–	1,000,000
Other long-term liabilities	–	8,274
Total liabilities	\$7,292,264	\$7,812,024
Commitments and contingencies (note 5)		

Edgar Filing: SIMULATIONS PLUS INC - Form 10-Q

Shareholders' equity (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 17,032,364 and 16,943,001 shares issued and outstanding	5,504	5,414
Additional paid-in capital	10,078,647	9,714,290
Retained earnings	11,421,484	9,812,498
Total shareholders' equity	\$21,505,635	\$19,532,202
Total liabilities and shareholders' equity	\$28,797,899	\$27,344,226

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,**

	Three months ended (Unaudited)		Nine months ended (Unaudited)	
	2016	2015	2016	2015
Net Revenues	\$6,012,193	\$5,942,082	\$16,014,539	\$14,602,464
Cost of revenues	1,194,815	1,132,695	3,541,903	3,308,277
Gross margin	4,817,378	4,809,387	12,472,636	11,294,187
Operating expenses				
Selling, general, and administrative	1,680,707	1,607,317	5,079,985	5,234,311
Research and development	348,427	348,285	1,161,124	981,633
Total operating expenses	2,029,134	1,955,602	6,241,109	6,215,944
Income from operations	2,788,244	2,853,785	6,231,527	5,078,243
Other income (expense)				
Interest income	4,553	4,391	13,507	13,394
Gain(loss) on currency exchange	7,733	(35,632 )	(35,490 )	(78,107 )
Total other income (expense)	12,286	(31,241 )	(21,983 )	(64,713 )
Income from operations before provision for income taxes	2,800,530	2,822,544	6,209,544	5,013,530
Provision for income taxes	(891,191 )	(970,122 )	(2,048,383 )	(1,661,972 )
Net Income	\$1,909,339	\$1,852,422	\$4,161,161	\$3,351,558
Earnings per share				
Basic	\$0.11	\$0.11	\$0.24	\$0.20
Diluted	\$0.11	\$0.11	\$0.24	\$0.20
Weighted-average common shares outstanding				
Basic	17,028,634	16,862,128	17,000,228	16,847,191
Diluted	17,227,540	17,073,155	17,219,835	17,070,334

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,**

	(Unaudited)	
	2016	2015
Cash flows from operating activities		
Net income	\$4,161,161	\$3,351,558
Adjustments to reconcile net income to net cash provided by operating activities		
Depreciation and amortization of property and equipment	148,442	168,585
Amortization of capitalized computer software development costs	735,579	748,730
Amortization of Intellectual Property	566,250	566,250
Stock-based compensation	234,616	230,501
Deferred income taxes	(4,910 )	377,666
(Increase) decrease in		
Accounts receivable	(2,988,866)	(1,347,791)
Revenues in excess of billings	(244,772 )	(368,170 )
Prepaid income taxes	(108,690 )	748,359
Prepaid expenses and other assets	93,554	7,106
Increase (decrease) in		
Accounts payable	(24,411 )	(56,838 )
Accrued payroll and other expenses	81,212	(357,397 )
Accrued bonus	(30,250 )	(48,000 )
Billings in excess of revenues	5,911	(253,318 )
Accrued income taxes	(43,602 )	178,894
Other liabilities	(14,894 )	(14,895 )
Deferred revenue	182,321	11,796
Net cash provided by (used in) operating activities	2,748,651	3,943,036
Cash flows from investing activities		
Purchases of property and equipment	(32,317 )	(35,620 )
Cash used to purchase Cognigen	-	(2,080,000)
Cash received in acquisition	-	190,184
Capitalized computer software development costs	(815,582 )	(976,350 )
Net cash provided by (used in) investing activities	(847,899 )	(2,901,786)
Cash flows from financing activities		
Payment of Dividends	(2,552,175)	(2,528,416)
Payments on Contracts Payable	(750,000 )	(750,000 )
Proceeds from the exercise of stock options	129,831	50,833
Net cash (used in) financing activities of continuing operations	(3,172,344)	(3,227,583)
Net increase (decrease) in cash and cash equivalents	(1,271,592)	(2,186,333)

Edgar Filing: SIMULATIONS PLUS INC - Form 10-Q

Cash and cash equivalents, beginning of year	8,551,275	8,614,929
Cash and cash equivalents, end of period	\$7,279,683	\$6,428,596
Supplemental disclosures of cash flow information		
Interest paid	\$-	\$-
Income taxes paid	\$2,186,159	\$320,707
Non-Cash Investing and Financing Activities		
Stock issued for acquisition of Cognigen Corporation	\$-	\$3,277,170
Creation of contract liability for acquisition of Cognigen Corporation	\$-	\$1,854,404

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

**Simulations Plus, Inc.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

May 31, 2016 and 2015

(Unaudited)

Note 1: GENERAL

This report on Form 10-Q for the quarter ended May 31, 2016, should be read in conjunction with the Company's annual report on Form 10-K for the year ended August 31, 2015, filed with the Securities and Exchange Commission ("SEC") on November 20, 2015. 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").

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. Recently, the Company has begun to explore 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, as of September 2, 2014, 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.

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 MedChem Designer™ program, and we do not foresee an end-of-life for any of them at this point). Amortization of software development costs amounted to \$735,759 and \$748,730 for the nine months ended May 31, 2016 and 2015, respectively, and amortization of software development costs was \$241,042 and \$258,679 for the three months ended May 31, 2016 and 2015, 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:

Level	Input Definition:
Input:	
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.

Edgar Filing: SIMULATIONS PLUS INC - Form 10-Q

The following table summarizes fair value measurements by level at May 31, 2016 for assets and liabilities measured at fair value on a recurring basis:

	<b>Level I</b>	<b>Level II</b>	<b>Level III</b>	<b>Total</b>
Cash and cash equivalents	\$7,279,683	\$-	\$-	\$7,279,683
Total	\$7,279,683	\$-	\$-	\$7,279,683

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 which 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.

### 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 nine months periods ended May 31, 2016 and 2015 was \$5,625 and was \$1,875 for each three-month period ended May 31, 2016 and 2015. Accumulated amortization as of May 31, 2016 was \$31,875.

On May 15, 2014, we bought out a royalty agreement with TSRL, Inc. of Ann Arbor, Michigan. The cost of \$6,000,000 is being amortized over 10 years under the straight-line method. Amortization expense for each of the nine months periods ended May, 2016 and 2015 was \$450,000 and was \$150,000 for each three-month period ended May 31, 2016 and 2015. Accumulated amortization as of May 31, 2016 and August 31, 2015 was \$1,225,000 and \$775,000, respectively. (See Note 4.)

Total amortization expense for intellectual property agreements for the three months ended May 31, 2016 and 2015 was \$151,875, and \$455,625 for the nine months ended May 31, 2016 and 2015. Accumulated amortization as of May 31, 2016 was \$1,256,875 and \$801,250 as of August 31, 2015.

### 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, 2016:

Edgar Filing: SIMULATIONS PLUS INC - Form 10-Q

	Amortization Period	Acquisition Value	Accumulated Amortization	Net book value
Customer relationships	Straight line 8 years	\$1,100,000	\$ 240,625	\$859,375
Trade Name-Cognigen	None	500,000	–	500,000
Covenants not to compete	Straight line 5 years	50,000	17,500	32,500
		\$1,650,000	\$ 258,125	\$1,391,875

Amortization expense for each of the three months periods ended May 31, 2016 and 2015 was \$36,875 and was \$110,625 for each nine-month periods ended May 31, 2016 and 2015. 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, 2016 and 2015 were as follows:

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>05/31/2016</b>	<b>05/31/2015</b>	<b>05/31/2016</b>	<b>05/31/2015</b>
Numerator:				
Net income attributable to common shareholders	\$ 1,909,339	1,852,422	\$ 4,161,161	\$ 3,351,558
Denominator:				
Weighted-average number of common shares outstanding during the period	17,028,634	16,862,128	17,000,228	16,847,191
Dilutive effect of stock options	198,906	211,027	219,607	223,143
Common stock and common stock equivalents used for diluted earnings per share	17,227,540	17,073,155	17,219,835	17,070,334

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 \$246,616 and \$230,501 for the nine months ended May 31, 2016 and 2015, respectively, and was \$114,367 and \$79,877 for the three months ended May 31, 2016 and 2015, 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 ASU No. 2014-09, *Revenue from Contracts with Customers* (“ASU No. 2014-09”). 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 April 2016, the FASB issued AS 2016-10, Revenue from Contracts with Customers (Topic 606), which amends certain aspects of the Board's new revenue standard, ASU 2014-09, Revenue from Contracts with Customers. The standard should be adopted concurrently with adoption of ASU 2014-09 which is effective for annual and interim periods beginning after December 15, 2017. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

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 has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

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 which include - the income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and forfeiture rate calculations. ASU 2016-09 will become effective for the Company in the first quarter of fiscal 2019. Early adoption is permitted in any interim or annual period. The Company is currently evaluating the impact of this guidance on its consolidated financial statements.

### Note 3: Property and Equipment

Property and equipment as of May 31, 2016 consisted of the following:

Equipment	\$487,459
Computer equipment	195,940
Furniture and fixtures	123,235
Leasehold improvements	103,598
Sub total	910,232
Less: Accumulated depreciation and amortization	(612,847)
Net Book Value	\$297,385

### NOTE 4: CONTRACTS PAYABLE

#### TSRL

Pursuant to the termination and non-assertion agreement with TSRL, the Company agreed to pay TSRL total consideration of \$6.0 million. The Company paid \$3.5 million on May 20, 2014, comprised of cash in the amount of \$2.5 million and the issuance of \$1 million worth of the Company's common stock - 164,745 shares of the Company's common stock based upon the April 25, 2014 closing price per share of \$6.07 (See note 2). According to the contract, the Company paid \$750,000 to TSRL in April 2015 and 2016 and will pay TSRL an additional \$1,000,000 in April

2017. The remaining payments scheduled, by year, are below.

Cognigen Acquisition Liability-Related Party

On September 2, 2014, the Company acquired Cognigen Corporation. As part of the above-discussed consideration payable to the former shareholders of Cognigen, the Company agreed that within three business days following the two-year anniversary of July 23, 2014 (the date of the Merger Agreement) and subject to any offsets, the Company will pay the former shareholders of Cognigen a total of \$1,854,404, comprised of \$720,000 of cash and the issuance of 170,014 shares of the Company's stock. The former shareholders of Cognigen are currently employed by the consolidated Company, one of whom serves as the President.

Future payments under the Agreements, which are non-interest-bearing, are due as follows:

As of the period ending May 31,	TSRL	Cognigen Acquisition Liability	Total
2017	\$ 1,000,000	\$ 1,854,404	\$ 2,854,404
Total	\$ 1,000,000	\$ 1,854,404	\$ 2,854,404
Less current portion	(1,000,000)	(1,854,404)	(2,854,404)
Contracts payable, net of current portion	\$ 0	\$ 0	\$ 0

Note 5: COMMITMENTS AND CONTINGENCIES

Employment Agreement

Effective September 1, 2014, the Company entered into an Employment Agreement with Walter S. Woltosz to serve as Chief Executive Officer of the Company (the “Woltosz Employment Agreement”). The Woltosz Employment Agreement had a one-year term. Under the terms of the Woltosz Employment Agreement, Mr. Woltosz was required to devote a minimum of 60% of his productive time to the position of Chief Executive Officer of the Company. He received annual compensation of \$180,000, was eligible to receive stock options to purchase up to 12,000 shares of the Company’s common stock under the 2007 Simulations Plus, Inc. Stock Option Plan, as determined by the Company’s Board of Directors, and was to be paid an annual performance bonus of up to 5% of the Company’s net income before taxes, not to exceed \$36,000. A copy of the Woltosz Employment Agreement was filed as an attachment to the 8-K filed with the Securities and Exchange Commission on September 4, 2014. On July 9, 2015, the Company renewed this employment agreement for another year on the same terms as the September 2014 agreement. A copy of the agreement was filed as an attachment to the 8-K filed with the Securities and Exchange Commission on July 15, 2015. Mr. Woltosz’ bonuses under these agreements were paid in September following each agreement’s term.

On September 2, 2014, Thaddeus H. Grasela, Jr., Ph.D., was appointed President of the Company, and the Company has entered into an Employment Agreement with Dr. Grasela (the “Grasela Employment Agreement”), which 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 stock options to purchase shares of the Company’s common stock under the 2007 Simulations Plus, Inc. Stock Option Plan, as determined by the Company’s Board of Directors, and is eligible to receive an annual performance bonus in an amount not to exceed 10% of base salary, to be determined by the Compensation Committee of the Company’s Board of Directors. On September 1, 2015 the Compensation Committee awarded a \$25,000 performance bonus to Dr. Grasela. This expense was accrued as an expense as of August 31, 2015. This bonus was paid in September 2015.

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. For the nine months ended May 31, 2016 and 2015, we incurred royalty expense of \$95,323 and \$58,187, respectively, and for the three months ended May 31, 2016 and 2015, we incurred royalty expense of \$44,485 and \$23,197, respectively.

Income taxes

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. We file income tax returns with the IRS and various state jurisdictions and India. 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 returns for fiscal years 2008 and 2009 remain open with regard to research and development 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 will be auditing the Company's tax return for 2014. The audit was started in October 2015 and has not been completed. The Company does not believe that this examination by the IRS will result in a significant change to our financial position or results of operations.

### Litigation

Except as described below, 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 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. On November 25, 2014, the plaintiff and the Company signed a stipulation of dismissal pursuant to which the plaintiff agreed to dismiss the Company without prejudice. The Company planned to prepare a dismissal with prejudice to be signed on behalf of the plaintiff in the event the plaintiff did not discover evidence during a nine-month period to and including August 31, 2015, that justified bringing the Company back into the litigation. The Company did not receive notification of any such discovery and is in the process of preparing documents for the plaintiff's final dismissal with prejudice.



## Note 6: SHAREHOLDERS' EQUITY

Dividend

The Company's Board of Directors declared cash dividends during fiscal years 2016 and 2015. The details of the dividends paid are in the following tables:

## FY2015

Record Date	Distribution Date	Number of Shares Outstanding on Record Date	Dividend per Share	Total Amount
11/7/2014	11/14/2014	16,841,114	\$ 0.05	\$ 842,056
1/26/2015	2/2/2015	16,852,117	\$ 0.05	\$ 842,606
5/11/2015	5/18/2015	16,875,117	\$ 0.05	\$ 843,754
7/23/2015	7/30/2015	16,943,001	\$ 0.05	\$ 847,150
Total				\$ 3,375,566

## 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
Total				\$ 2,552,175

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.

#### Qualified Incentive Stock Options (Qualified ISO)

As of May 31, 2016, employees hold Qualified ISO to purchase 965,600 shares of common stock at exercise prices ranging from \$1.00 to \$9.82, which were granted prior to May 31, 2016.

Transactions in FY16	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life
Outstanding, August 31, 2015	621,000	\$ 5.01	6.10
Granted	412,100	\$ 9.71	
Exercised	(89,363 )	\$ 1.48	
Cancelled/Forfeited	(27,487 )	\$ 7.66	
Outstanding, May 31, 2016	916,250	\$ 7.39	7.79
Exercisable, May 31, 2016	213,590	\$ 3.90	4.22

Non-Qualified Stock Options (Non-Qualified ISO)

As of May 31, 2016, the outside members of the Board of Directors hold options to purchase 49,350 shares of common stock at exercise prices ranging from \$1.67 to \$6.75, which were granted prior to May 31, 2016.

Transactions in FY16	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life
Outstanding, August 31, 2015	49,350	\$ 5.52	7.78
Granted	0	\$ 0.00	
Exercised	0	\$ 0.00	
Outstanding, May 31, 2016	49,350	\$ 5.52	6.99
Exercisable, May 31, 2016	27,200	\$ 4.70	5.56

The weighted-average remaining contractual life of options outstanding issued under the Plan, both Qualified ISO and Non-Qualified SO, was 7.75 years at May 31, 2016. The exercise prices for the options outstanding at May 31, 2016 ranged from \$1.00 to \$9.82, 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	88,000	2.30 years	\$ 1.03	88,000	2.30 years	\$ 1.03
\$1.51	\$3.00	3,600	3.94 years	\$ 2.2	3,600	3.94 years	\$ 2.20
\$3.01	\$4.50	28,500	3.12 years	\$ 3.35	28,500	3.12 years	\$ 3.35
\$4.51	\$6.00	74,000	2.91 years	\$ 5.48	41,600	2.96 years	\$ 5.42
\$6.01	\$7.50	367,200	8.22 years	\$ 6.85	79,090	7.91 years	\$ 6.86
\$7.50	\$9.82	404,300	9.76 years	\$ 9.71	0	—	—
		<b>965,600</b>	<b>7.75 years</b>	<b>\$ 7.29</b>	<b>240,790</b>	<b>4.49 years</b>	<b>\$ 3.99</b>

## NOTE 7: RELATED PARTY TRANSACTIONS

As of May 31, 2016, included in bonus expenses to officers was \$90,750, of which \$45,000 was accrued bonus representing an estimated quarterly amount of bonus payable to the Corporate Secretary, Virginia Woltosz, as part of the terms of the sale of Words+ to Simulations Plus in 1996, and \$27,000 accrued bonus representing an estimated amount of bonus payable to our Chief Executive Officer, Walter Woltosz as part of his current employment

agreement, and \$18,750 accrued bonus representing as estimated amount of bonus payable to our President, Thaddeus Grasela as part of his current employment agreement.

#### NOTE 8: CONCENTRATIONS AND UNCERTAINTIES

Revenue concentration shows that international sales accounted for 43.8% and 39.5% of net sales for the nine months ended May 31, 2016 and 2015, respectively. 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. Three customers accounted for 8% (a dealer account in Japan representing various customers), 7%, and 5% of sales for the nine months ended May 31, 2015.

Accounts receivable concentrations shows that two customers comprised 15% and 11% (a dealer account in Japan representing various customers) of accounts receivable at May 31, 2016 compared to two customers (a dealer account in Japan representing various customers) that comprised 18% and 16% of accounts receivable at May 31, 2015.

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, 2016 and 2015 (in thousands):

## 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

## Three months ended May 31, 2015

	Lancaster	Buffalo	Eliminations	Total
Net Revenues	\$4,541	\$1,401		\$5,942
Income (loss) from operations	\$2,477	\$377		\$2,854
Total assets	\$26,336	\$8,814	\$(7,238)	\$27,912
Capital expenditures	\$7	\$10		\$17
Capitalized software costs	\$193	\$53		\$246
Depreciation and Amortization	\$413	\$91		\$504

## Nine months ended May 31, 2016

	Lancaster	Buffalo	Eliminations	Total
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

## Nine months ended May 31, 2015

	Lancaster	Buffalo	Eliminations	Total
Net Revenues	\$10,795	\$3,807		\$14,602

Edgar Filing: SIMULATIONS PLUS INC - Form 10-Q

Income (loss) from operations	\$4,451	\$627		\$5,078
Total assets	\$26,336	\$8,814	\$(7,238)	) \$27,912
Capital expenditures	\$23	\$14		\$37
Capitalized software costs	\$860	\$116		\$976
Depreciation and Amortization	\$1,211	\$273		\$1,484

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, 2016 and 2015 were as follows (in thousands):

Three months ended May 31, 2016

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

Three months ended May 31, 2015

	North America	Europe	Asia	South America	Total
Lancaster	\$2,239	\$1,287	\$1,003	\$12	\$4,541
Buffalo	\$1,401	\$-	\$-	\$-	\$1,401
Total	\$3,640	\$1,287	\$1,003	\$12	\$5,942

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

Nine months ended May 31, 2015

	North America	Europe	Asia	South America	Total
Lancaster	\$5,029	\$3,201	\$2,552	\$13	\$10,795
Buffalo	\$3,807	\$-	\$-	\$-	\$3,807
Total	\$8,836	\$3,201	\$2,552	\$13	\$14,602

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 \$168,654 and \$179,591 for the nine months ended May 31, 2016 and 2015, respectively, and \$61,028 and \$56,745 for the three months ended May 31, 2016 and 2015, respectively.





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**

The Company is a premier developer of groundbreaking drug discovery and development simulation and modeling software. Our software is licensed to major pharmaceutical, biotechnology, agrochemical, and food industry companies and to regulatory agencies worldwide for use in the conduct of model-based drug development and the study of environmental toxicants. We also provide consulting services ranging from early drug discovery through preclinical and clinical development and regulatory submissions. Recently, we have been exploring the application of some of our advanced machine-learning technologies for problems in aerospace and healthcare outside of our traditional markets. The Company is headquartered in Southern California, with offices in Buffalo, New York. Our common stock trades on the NASDAQ Capital Market under the symbol “SLP.”

Our clinical-pharmacology-based consulting services include pharmacokinetic and pharmacodynamic modeling, clinical trial simulations, data programming, and technical writing services in support of regulatory submissions. We have also developed software for harnessing cloud-based computing in support of modeling and simulation activities and secure data archiving, and we provide consulting services to improve interdisciplinary collaborations and R&D productivity.

We are a global leader focused on improving the ways scientists use knowledge and data to predict the properties of new molecules and the outcomes of clinical trials with pharmaceutical and biotechnology agents. We are one of only two global companies who provide a wide range of early discovery, preclinical, and clinical consulting services and software. Our innovations in integrating new and existing science in medicinal chemistry, computational chemistry, computer science, pharmaceutical science, biology, and physiology into our software have made us the leading software provider for physiologically based pharmacokinetics (PBPK) modeling and simulation. Our powerful machine-learning technology that has resulted in best-in-class predictions in pharmaceutical chemistry is now being successfully tested for solving several complex problems in the aerospace and healthcare industries.

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



## PRODUCTS

### General

We currently offer seven 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™); and one program called KIWI™ that provides an integrated platform for data analysis and reporting through our proprietary secure cloud. During the first fiscal quarter of FY2016, we announced the development of a major new software product called PKPlus™ for noncompartmental and compartmental pharmacokinetic analysis and reporting, which is further described below.

### 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 software of its type in pharmaceutical companies, the U.S. Food and Drug Administration (FDA), the U.S. National Institutes of Health (NIH), and other government agencies in the U.S. and other countries. The U.S. 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 is at our own expense, while other members are compensated for their work; however, we are a full member with access to all of the data and discussions of all other members. We believe our investment to participate in this initiative enables 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 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 highly successful first year, the RCA was renewed for its second year in September 2015.

We were awarded another RCA by the FDA in September 2015, this time 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 slow dissolution/decomposition of the microsphere carrier material that gradually releases the active drug over periods as long as weeks or months.

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.

During May and June we submitted proposals in response to two new solicitations issued by the FDA. One is to incorporate PBPK modeling such as we have in GastroPlus with the statistical analysis methods traditionally used in clinical trial data analysis (done with simple statistical models rather than detailed PBPK models). This would involve integrating the expertise in our science teams in Lancaster (PBPK) and Buffalo (pharmacometrics – the statistical approaches currently used for Phase 2 and 3 analyses), further exploiting the synergies between our two divisions.

The other solicitation is to deal with supersaturating drug delivery systems (SDDSs), which dissolve rapidly in the stomach at low pH where their solubility is high, then become supersaturated (concentration is greater than solubility) when the drug moves into the intestinal tract where pH is much higher and solubility is lower.

The solicitations indicate that up to two contracts will be awarded for each project. The funding for each award is \$250,000 per year for up to two years, for a potential total of \$500,000 for each project, or up to a total of \$1 million over two years if we were to win both. We believe our proposals are strong and we anticipate receiving awards for one or both projects. Both of these projects would result in substantially expanding the capabilities of our GastroPlus software. Announcement of awards is expected by September.

In April 2015, we released Version 9.0 of GastroPlus. This was the largest single upgrade we've made to the program to date, and the added level of science and technology enabled valuable new functionalities that we believe provide the most advanced decision-making tool for preclinical and early clinical trial simulation and modeling analysis available today. Several of the significant enhancements include:

- ability to simulate the absorption and distribution of biologics (antibodies and proteins)
- ability to simulate dosing to the skin, including patches, creams, ointments, and subcutaneous injections
- tighter integration with our ADMET Predictor™ software to increase the utility of the program in early drug discovery.

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 & development process, while also helping us further penetrate the biopharmaceuticals, food, cosmetics, and general toxicology markets.

We are now finalizing the development of version 9.5 of GastroPlus, which will add a number of new capabilities and will refine and enhance some of the existing capabilities in the program, including intramuscular dosing, simulation of antibody-drug conjugates, additional animal physiologies, enhanced report generation, and enhancements to the PBPK tissue models. We expect to release version 9.5 before the end of FY2016.

#### 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, or capsule) 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 dissolution rate for various formulations, (2) reduce the number of cut-and-try attempts to design new drug formulations, and (3) design *in vitro* dissolution experiments to better mimic *in vivo* (animal and human) conditions. Version 5.0 of DDDPlus, which adds a number of significant enhancements, was released in April. This version adds 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.

#### MembranePlus™

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 a simulation 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. A few initial sales of MembranePlus have been made. Like DDDPlus was ten years ago, this program is a very new concept that requires educating scientists on how and why to use it, and our marketing and sales program has been tasked with providing that training.

#### PKPlus™

On October 15, 2015 we announced the development 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 models as well as noncompartmental analysis (NCA) for intravenous and extravascular (oral, dermal, ocular, pulmonary, etc.) doses. The original PKPlus module in GastroPlus was not designed to meet all of the requirements for performing these analyses for Phase 2 and 3 clinical trials and to produce report-quality output for regulatory submissions. The new standalone PKPlus program is being 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. The program has been in development for about 23 months, and is nearing completion. We believe the potential number of users for PKPlus is large and that it has the potential to eventually become one of our leading revenue producers. We expect to release PKPlus in our fourth fiscal quarter.

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 forms) 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.

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 7.2, released in May, 2015) contains updated cytochrome P450 enzyme kinetics models that are seamlessly integrated into the recently released GastroPlus Version 9.0, enhancing the synergy between predicted properties and PBPK simulations and enabling discovery chemists – a new group of potential users – to use PBPK simulations. It also contains two new models related to human liver microsomal (HLM) stability, an experiment that is routinely run on newly synthesized compounds in the pharmaceutical industry. These updated models illustrate our commitment to providing the best predictive models in the industry.

We are now in final development and testing of ADMET Predictor 8.0, which 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. We expect to release version 8.0 during the fourth fiscal quarter of FY2016.

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.

Potential new markets for machine learning

We are currently investigating applications of this 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 in these three 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.

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 ~150 predictions that are available. Over 16,000 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 ~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. We are not aware of any other software company that has demonstrated the ability of their software in this way.

#### 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 1.5 was released in March 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.

*Contract Research and Consulting Services*

Our scientists and engineers have world-class expertise in drug absorption via various dosing routes (oral, intravenous, ocular, nasal/pulmonary, and dermal), pharmacokinetics, and pharmacodynamics. They have been speakers or presenters at over 150 scientific meetings worldwide in the past four years. We frequently conduct contracted studies for large customers (including the 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 currently are working with the FDA on three different Research Collaboration Agreements (RCAs): the two funded efforts for the ocular model and long-acting injectable microspheres and the unfunded IVIVC effort, all described above under “GastroPlus”.

**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 the 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.

At meetings held in 2014 by the FDA and other regulatory agencies, such agencies emphasized an interest in bringing mechanistically detailed physiologically based pharmacokinetics (PBPK) into clinical pharmacology. The recent \$500,000/2-year solicitation from the FDA demonstrates the significant interest the agency has in pushing this technology forward.

Because of the synergies achieved through the integration of our Buffalo division (Cognigen) into Simulations Plus, our first full fiscal year of combined operations resulted in significantly increased revenues and earnings. Our clinical pharmacometricians in Buffalo, supported by our consulting team in California, are learning to use the PBPK modeling capabilities of GastroPlus and are performing such studies under new and expanded contracts with pharmaceutical customers. Our proposal to the FDA for combining PBPK modeling with traditional population-based

statistical methods relies on combining the expertise of our California and New York divisions, made possible by our acquisition of Cognigen Corporation nearly two years ago.

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

## **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 were from industry and FDA scientists; some were from our staff. In addition, more than 50 peer-reviewed scientific journal articles are 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 and New York, with locations in Lancaster, Petaluma, San Jose, San Diego, and Buffalo. In addition, we have one team member working out of North Carolina and our Chief Executive Officer works primarily from Auburn, Alabama.

## 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 upcoming 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, and we believe sales will begin quickly after the product is released in the fourth quarter. 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 that the success of our two NCE projects in which we successfully designed, synthesized, and tested new lead molecules to treat malaria as well as COX-2/COX-1 will further promote the abilities of our ADMET Design Suite for rapid and cost-effective design of lead compounds. We expect the completely refactored ADMET Predictor 8.0 version with its fresh look and expanded features will generate increased interest in drug discovery and early drug development teams.

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

We actively seek acquisitions to expand the pharmaceutical software and services business. We plan to continue our efforts to find strategic targets and alliances that will enhance our position in the industry, and to pursue the application of our machine-learning technology to new industries.





## **STRATEGY**

Our business strategy is to do the things we need to do to promote growth both organically (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.

On July 23, 2014, we signed a merger agreement with Cognigen Corporation of Buffalo, New York. The merger closed on September 2, 2014, and Cognigen became our wholly owned subsidiary. We believe the combination of Simulations Plus and Cognigen provides substantial future potential based on the complementary strengths of each of the companies. It is our intent to continue to search for acquisition opportunities that are compatible with our current businesses and that are accretive, i.e., adding to both revenues and earnings.

In the fiscal year ended August 31, 2015 we distributed \$0.20 per share in dividends to our shareholders. In November 2015, February 2016, and May 2016 the board declared quarterly dividends of \$0.05 per share. We anticipate future dividends to be \$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, 2016 and 2015.***

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

Edgar Filing: SIMULATIONS PLUS INC - Form 10-Q

	5/31/16		5/31/15	
Net revenues	\$6,012	100.0%	\$5,942	100.0%
Cost of revenues	1,195	19.9	1,132*	19.1
Gross profit	4,817	80.1	4,809	80.9
Selling, general and administrative	1,681	28.0	1,607*	27.0
Research and development	348	5.8	348	5.9
Total operating expenses	2,029	33.8	1,955	32.9
Income from operations	2,788	46.4	2,854	48.0
Other income	12	0.2	(31 )	(0.5 )
Income from operations before taxes	2,800	46.2	2,822	47.5
(Provision for) income taxes	(891 )	(14.8 )	(970 )	(16.3 )
Net income	\$1,909	31.8%	\$1,852	31.2%

\* Numbers in the prior year have been reclassified to conform to the current year presentation

Net Revenues

Consolidated net revenues increased by 1.2% or \$70,000 to \$6.012 million in the third fiscal quarter of Fiscal Year 2016 (“3QFY16”) from \$5.942 million in the third fiscal quarter of Fiscal Year 2015 (“3QFY15”). This net increase was due to a \$123,000 increase in revenues generated by our Lancaster Division, representing a 2.7% increase over 3QFY15, offset by a 3.8% decrease in revenues of our Buffalo Division of \$53,000, to \$1.348 million in 3QFY16 from \$1.401 million in 3QFY15. Consolidated software and software-related sales increased \$123,000 or 2.8%, while consolidated consulting and analytical study revenues decreased \$53,000 or 3.5% over 3QFY15. Buffalo revenues were impacted by a combination of cancellations of consulting contracts caused by drug failures in clinical trials as well as delayed trials by the sponsors.

Cost of Revenues

Consolidated cost of revenues increased by \$63,000, or 5.5%, in 3QFY16 to \$1.195 million from \$1.132 million in 3QFY15. \$53,000 of the increase was training-revenues-related costs. There were no other significant changes to consolidated cost of revenues in 3QFY16 compared to 3QFY15.

Cost of Revenues as a percentage of revenue remained substantially constant, increasing slightly by 0.9% in 3QFY16 to 19.9% as compared to 18.8% in 3QFY15.

Gross Profit

Consolidated gross profits remained nearly constant, increasing \$8,000 or 0.02%, to \$4.817 million in 3QFY16 from \$4.809 million in 3QFY15. Our Lancaster Division accounted for a \$117,000 increase, which came mainly from increased software license sales and related training revenues, while our Buffalo Division saw a decrease of \$109,000 due to a combination of lower revenues and increased Cost of Revenues. Consolidated Gross profit as a percentage of revenues remained substantially constant, increasing 0.2% to 80.1% in 3QFY16 from 81.2% in 3QFY15.

Selling, General and Administrative Expenses

Selling, general, and administrative (SG&A) expenses increased \$74,000, or 3.5%, to \$1.681 million in 3QFY16, from \$1.607 million in 3QFY15.

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

- Advertising increased by \$30,000 – we increased our web presence and incurred other advertising-related costs
- Professional fees were up \$55,000 – this was the result of tax preparation/review and accounting for compliance-related issues

Major Decreases – Commission expenses decreased \$27,000 on lower commissionable revenues. There were no other individually significant decreases in this quarter compared to last year.

Research and Development

We incurred approximately \$617,000 of research and development costs during 3QFY16. Of this amount, \$269,000 was capitalized software development costs and \$348,000 was expensed. We incurred approximately \$594,000 of research and development costs during 3QFY15. Of this amount, \$246,000 was capitalized software development costs and \$348,000 was expensed.

Other income (expense)

Other income was \$12,000 compared to a loss of \$31,000 in 3QFY15. Foreign currency exchange accounted for \$8,000 of the increase, \$43,000 more in 3QFY16 compared to a \$35,000 loss in 3QFY15. The change is mainly due to the dollar strengthening in relation to the Japanese yen. Interest income remained nearly constant at \$4600 compared to \$4300 in 3QFY15.

Provision for Income Taxes

The provision for income taxes was \$891,000 for 3QFY16 compared to \$970,000 for 3QFY15. Our effective tax rate decreased 2.9% to 31.8% in 3QFY16 from 34.7% in 3QFY15. This decrease is a result of higher tax credits in 3QFY16.

Net Income

Net income increased by \$57,000, or 3.1%, in 3QFY16 to \$1.909 million from \$1.852 million in 3QFY15. Net earnings from our Lancaster division was \$1.778 million, up 11.4% from \$1.596 million in 3QFY15. Net earnings for our Buffalo division were \$131,000, a decrease of \$125,000 or 48.9% from \$256,000 in 3QFY15; we attribute this decrease to the impact of the combination of the cancellations of consulting contracts caused by drug failures in clinical trials as well as delayed trials by the sponsors.

*Comparison of Nine Months Ended May 31, 2016 and 2015*

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			
	5/31/16		5/31/15	
Net sales	\$16,015	100.0%	\$14,602	100.0%
Cost of revenues	3,542	22.1	3,308 *	22.7
Gross profit	12,473	77.9	11,294	77.3
Selling, general and administrative	5,080	31.7	5,234 *	35.9
Research and development	1,161	7.3	982	6.7
Total operating expenses	6,241	39.0	6,216	42.6
Income from operations	6,232	38.9	5,078	34.8
Other income	(22 )	(0.13 )	(65 )	(0.44 )
Income from operations before taxes	6,210	38.8	5,014	34.3
(Provision for) income taxes	(2,048 )	(12.8 )	(1,662 )	(11.4 )
Net income	\$4,161	26.0%	\$3,352	23.0 %

\* Numbers in the prior year have been reclassified to conform to the current year presentation

Net Revenues

Consolidated net revenues increased by 9.7% or \$1.412 million to \$16.014 million in the first nine months of Fiscal Year 2016 (“9moFY16”) from \$14.602 million in the first nine months of Fiscal Year 2015 (“9moFY15”). \$485,000 of this increase was from revenues generated by our Buffalo Division, representing a 12.7% increase over 9moFY15. Net revenues of the Lancaster Division increased \$927,000, or 8.6%, to \$11.722 million for 9moFY16 from \$10.795 million in 9moFY15. Consolidated software and software-related sales increased \$923,000, or 8.9%, in 9moFY16, while consolidated consulting and analytical study revenues increased \$492,000, or 11.5%, over 9moFY15.

Cost of Revenues

Consolidated cost of revenues increased by \$234,000 in 9moFY16 to \$3.542 million from \$3.308 million in 9moFY15. The increase came mainly from additional training-revenue-related costs of \$69,000, and first-year bonuses of \$139,000 paid to employees in our Buffalo Division. There were no other significant changes to consolidated expenses in 9moFY16 compared to 9moFY15. Consolidated cost of revenues as a percentage of revenue decreased 0.6% from 22.7% in 9moFY15 to 22.1% in 9moFY16.

Gross Profit

Consolidated gross profit increased \$1.178 million or 10.4%, to \$12.473 million in 9moFY16 from \$11.294 million in 9moFY15. \$297,000 of this increase in gross profit is from our Buffalo Division, which showed a 59.1% gross margin on \$4.292 million in revenues for 9moFY16. Our Lancaster Division accounted for \$881,000 of the increase, which came mainly from increased software license sales. The Lancaster Division showed an 84.8% gross margin for the nine-month period.

Selling, General and Administrative Expenses

Selling, general, and administrative (SG&A) expenses decreased \$155,000, or 2.9%, to \$5.080 million in 9moFY16 from \$5.23 million in 9moFY15. SG&A as a percent of revenues decreased to 31.7% from 35.9% in 9moFY15.

The major increases in SG&A expense were:

- Advertising increase by \$68,000 - we increased our web presence and incurred other advertising-related costs
- Marketing labor increased by \$50,000 - more time was spent by scientific personnel on marketing-related activities
- Software License expenses increased \$51,000 due to new outside software licensing based on increased software volume tiers
- Professional fees were up \$72,000 – this was the result of the additional costs of the consolidated entity and other tax and accounting compliance-related issues

The major decreases in SG&A expense were:

Consulting Fees decreased by \$397,000 - in 9moFY15, we paid approximately \$400,000 in one-time fees and expenses to our financial advisor/business broker related to the Cognigen acquisition. There were no such expenses in the current reporting period.

#### Research and Development

We incurred approximately \$1.974 million of research and development costs during 9moFY16. Of this amount, \$814,000 was capitalized software development costs and \$1.161 million was expensed. We incurred approximately \$1.957 million of research and development costs during 9moFY15. Of this amount, \$976,000 was capitalized software development costs and \$982,000 was expensed.

#### Other income (expense)

Foreign currency showed a \$35,000 loss for 9MoFY16, a \$43,000 increase compared to the \$78,000 loss in 9moFY15. The change is mainly due to the dollar strengthening in relation to the Japanese yen.

#### Provision for Income Taxes

The provision for income taxes was \$2.049 million for 9moFY16 compared to \$1.662 million for 9moFY15, an increase of \$386,000, or 23.1%. Our effective tax rate decreased slightly to 33.0% in 9moFY16 from 33.1% in 9moFY15. This decrease is a result of increased tax credits in 9moFY16.

#### Net Income

Net income increased by \$810,000, or 24.2%, to \$4.161 million in 9moFY16 from \$3.352 million in 9moFY15. The increase comes from two main sources: increased revenues of \$1.412 million; and reduced SG&A expense in 2016, since in 2015 we incurred approximately \$400,000 of one-time consulting costs associated with the Cognigen acquisition.

#### **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 eight 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

Our risk from exposure to financial markets is limited to foreign exchange variances and fluctuations in interest rates. We may be subject to some foreign exchange risks. Most of our business transactions are in U.S. dollars, although we generate significant revenues from customers overseas. The exception is that we have been compensated in Japanese yen by Japanese customers and PRC Yuan by Chinese customers. In the future, if foreign currency transactions increase significantly, then we may mitigate this effect through price adjustments and/or foreign currency forward contracts whose market-to-market gains or losses are recorded in "Other Income or expense" at the time of the transaction. To date, exchange rate exposure has not resulted in a material impact.

### Item 4. Controls and Procedures

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.



Based on management's evaluation (with the participation of our chief executive officer and chief financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting, as defined in Exchange Act Rule 13a-15(f). Our internal controls over financial reporting are designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of condensed financial statements for external purposes in accordance with generally accepted accounting principles.

No changes were made in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during our most recent fiscal quarter that have materially affected or are reasonably likely to materially affect, our internal controls over financial reporting.

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. On November 25, 2014, the plaintiff and the Company signed a stipulation of dismissal pursuant to which the plaintiff agreed to dismiss the Company without prejudice. The Company planned to prepare a dismissal with prejudice to be signed on behalf of the plaintiff in the event the plaintiff did not discover evidence during a nine month period to and including August 31, 2015 that justified bringing the Company back into the litigation. The Company did not receive notification of any such discovery and is in the process of preparing documents for the plaintiff's final dismissal with prejudice.

### Item 1A Risk factors

Not applicable

### 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 May 23, 2013. (8)
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 August 22, 2013. (9) (†)
10.7	Employment Agreement by and between the Company and Walter S. Woltosz, dated as of August 28, 2014. (12) (†)
10.8	Employment Agreement by and between the Company and Thaddeus H Grasela Jr. dated as of September 2, 2014. (12) (†)
10.9	Employment Agreement by and between the Company and Walter S. Woltosz, dated as of July 9, 2015. (14) (†)
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.
- \* Filed herewith
- \*\* Furnished herewith
- (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.

**SIGNATURE**

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 14, 2016.

Simulations Plus, Inc.

Date: July 14, 2016 By: /s/ John R Kneisel  
John R. Kneisel  
Chief Financial Officer