SIMULATIONS PLUS INC
Form 10-Q
January 09, 2019

Table of Contents

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 **November 30, 2018**

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 10th Street West

Lancaster, CA 93534-7059

(Address of principal executive offices including zip code)

(661) 723-7723

(Registrant's telephone number, including area code)

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
Emerging Growth Company	

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

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

The number of shares outstanding of the registrant’s common stock, par value $0.001 per share, as of January 9, 2019 was 17,459,770; no shares of preferred stock were outstanding.

Simulations Plus, Inc.

FORM 10-Q

For the Quarterly Period Ended November 30, 2018

Table of Contents

PART I. FINANCIAL INFORMATION

		Page
Item 1.	Condensed Financial Statements	
	Condensed Consolidated Balance Sheets at November 30, 2018 (unaudited) and August 31, 2018 (audited)	3
	Condensed Consolidated Statements of Operations for the three months ended November 30, 2018 and 2017 (unaudited)	4
	Condensed Consolidated Statements of Cash Flows for the three months ended November 30, 2018 and 2017 (unaudited)	5
	Notes to Condensed Consolidated Financial Statements (unaudited)	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Result of Operations	22
	General	22
	Result of Operations	32
	Liquidity and Capital Resources	33
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	34
Item 4.	Controls and Procedures	34

PART II. OTHER INFORMATION

Item 1.	Legal Proceedings	35
Item 1A.	Risk Factors	35
Item 2.	Changes in Securities	35

Item 3. Defaults upon Senior Securities 35

Item 4. Mine Safety Disclosures 35

Item 5. Other Information 35

Item 6. Exhibits 36

Signature 37

Part I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements
SIMULATIONS PLUS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	(Unaudited) November 30, 2018	(Audited) August 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$9,352,238	$9,400,701
Accounts receivable, net of allowance for doubtful accounts of $0	5,287,126	5,514,528
Revenues in excess of billings	2,259,610	1,985,596
Prepaid income taxes	–	312,593
Prepaid expenses and other current assets	502,063	610,439
Total current assets	17,401,037	17,823,857
Long-term assets		
Capitalized computer software development costs, net of accumulated amortization of $11,363,375 and $11,095,903	4,549,084	5,152,594
Property and equipment, net (note 4)	302,431	335,224
Intellectual property, net of accumulated amortization of $3,251,876 and $3,019,584	5,723,124	5,905,416
Other intangible assets net of accumulated amortization of $941,875 and $852,500	3,548,125	3,637,500
Goodwill	10,387,198	10,387,198
Other assets	37,227	37,227
Total assets	$41,948,226	$43,279,016
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$218,151	$351,605
Accrued payroll and other expenses	1,218,068	1,152,176
Income taxes payable	168,220	–
Current portion - Contracts payable (note 5)	2,750,000	2,556,644
Billings in excess of revenues	271,937	384,603
Deferred revenue	453,984	381,928
Total current liabilities	5,080,360	4,826,956
Long-term liabilities		
Deferred income taxes, net	2,922,457	3,195,139

Payments due under Contracts payable (note 5)	1,622,484	3,334,296
Total liabilities	9,625,301	11,356,391
Commitments and contingencies (note 6)		
Shareholders' equity (note 7)		
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 17,459,770 and 17,416,445 shares issued and outstanding	7,461	7,417
Additional paid-in capital	14,055,994	13,453,668
Retained earnings	18,259,470	18,461,540
Total shareholders' equity	32,322,925	$31,922,625
	$(0)	–
Total liabilities and shareholders' equity	$41,948,226	$43,279,016

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

SIMULATIONS PLUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

For the three months ended November 30,

	Unaudited	
	2018	2017
Revenues	$7,535,903	$7,068,782
Cost of revenues	2,200,371	1,735,608
Gross margin	5,335,532	5,333,174
Operating expenses		
Selling, general, and administrative	2,719,151	2,408,514
Research and development	529,636	360,817
Total operating expenses	3,248,787	2,769,331
Income from operations	2,086,745	2,563,843
Other income (expense)		
Interest income	3,672	4,310
Interest expense	(38,188)	(38,470)
Gain (loss) from sale of assets	–	–
Loss on currency exchange	(30,611)	(12,679)
Total other income (expense)	(65,127)	(46,839)
Income before provision for income taxes	2,021,618	2,517,004
Provision for income taxes	(485,671)	(800,999)
Net Income	$1,535,947	$1,716,005
Earnings per share		
Basic	$0.09	$0.10
Diluted	$0.09	$0.10
Weighted-average common shares outstanding		
Basic	17,421,838	17,282,132
Diluted	17,997,735	17,859,683

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

4

SIMULATIONS PLUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

For the three months ended November 30,

	(Unaudited)	
	2018	2017
Cash flows from operating activities		
Net income	$1,535,947	$1,716,005
Adjustments to reconcile net income to net cash provided by operating activities		
Depreciation and amortization	694,789	638,504
Change in value of contingent consideration	38,188	38,188
Stock-based compensation	244,935	166,994
Deferred income taxes	(41,701)	(135,500)
(Increase) decrease in		
Accounts receivable	227,402	(1,182,099)
Revenues in excess of billings	(274,014)	119,840
Prepaid income taxes	312,593	462,443
Prepaid expenses and other assets	108,376	108,049
Increase (decrease) in		
Accounts payable	(133,471)	(99,077)
Accrued payroll and other expenses	65,892	101,772
Billings in excess of revenues	(112,666)	385,275
Accrued income taxes	168,220	404,600
Deferred revenue	(222,769)	(83,712)
Net cash provided by operating activities	2,611,721	2,641,282
Cash flows used in investing activities		
Purchases of property and equipment	(1,255)	(47,276)
Purchases of intellectual property	(50,000)	–
Capitalized computer software development costs	(364,664)	(507,090)
Net cash used in investing activities	(415,919)	(554,366)
Cash flows used in financing activities		
Payment of dividends	(1,045,073)	(1,037,088)
Payments on Contracts Payable	(1,556,644)	(247,328)
Proceeds from the exercise of stock options	357,452	27,537
Net cash used in financing activities	(2,244,265)	(1,256,879)
Net increase (decrease) in cash and cash equivalents	(48,463)	830,037
Cash and cash equivalents, beginning of year	9,400,701	6,215,718
Cash and cash equivalents, end of period	$9,352,238	$7,045,755

Supplemental disclosures of cash flow information		
Income taxes paid	$16,357	$34,500

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

Simulations Plus, Inc.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

November 30, 2018 and 2017

(Unaudited)

NOTE 1: GENERAL

This report on Form 10-Q for the quarter ended November 30, 2018, should be read in conjunction with the Company's annual report on Form 10-K for the year ended August 31, 2018, filed with the Securities and Exchange Commission (“SEC”) on November 14, 2018. 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. Simulations Plus, Inc., acquired DILIsym Services, Inc. (DILIsym) as a wholly owned subsidiary pursuant to a stock purchase agreement dated May 1, 2017. On June 1, 2017, the Company consummated the acquisition of all outstanding equity interests of DILIsym pursuant to the terms of the Stock Agreement, with DILIsym becoming a wholly owned subsidiary of the Company. (Collectively, “Company”, “we”, “us”, “our”)

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, and as of June 1, 2017, the accounts of DILIsym Services, Inc. All significant intercompany accounts and transactions are eliminated in consolidation.

Estimates

Our 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

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09 and its related amendments regarding Accounting Standards Codification Topic 606 (ASC Topic 606), *Revenue from Contracts with Customers*. The standard provides principles for recognizing revenue for the transfer of promised goods or services to customers with the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also provides guidance on the recognition of incremental costs related to obtaining customer contracts. We adopted ASC Topic 606, effective September 1, 2018, utilizing the modified retrospective method. This approach was applied to contracts that were in process as of September 1, 2018, and the corresponding incremental costs of obtaining those contracts, which resulted in a cumulative effect adjustment to the opening balance of retained earnings at the date of adoption. The adoption of this ASU primarily impacts the timing of our revenue recognition for certain sales contracts, the capitalization and amortization of incremental costs of obtaining a contract, and related disclosures. The reported results for fiscal year 2019 reflect the application of ASC Topic 606, while the reported results for fiscal year 2018 are not adjusted and continue to be reported under ASC Topic 605.

We generate revenue primarily from the sale of software licenses and providing consulting services to the pharmaceutical industry for drug development.

The Company determines revenue recognition through the following steps:

i. Identification of the contract, or contracts, with a customer
ii. Identification of the performance obligations in the contract
iii. Determination of the transaction price
iv. Allocation of the transaction price to the performance obligations in the contract
v. Recognition of revenue when, or as, the Company satisfies a performance obligation

Deferred Commissions

Sales commissions earned by our sales force and our commissioned sales representatives are considered incremental and recoverable costs of obtaining a contract with a customer. Sales commissions for new contracts are deferred and then amortized on a straight-line basis over a period of benefit. We determined the period of benefit by taking into consideration our customer contracts, our technology and other factors. Sales commissions for renewal contracts are deferred and then amortized on a straight-line basis over the related contractual renewal period. Amortization expense is included in sales and marketing expenses on the condensed consolidated statements of operations.

We apply the practical expedient in ASC Topic 606 to expense costs as incurred for sales commissions when the period of benefit would have been one year or less. Most of our contracts are of a duration of one year or less, few, if any of the longer-term contracts have commissions associated with them.

Practical Expedients and Exemptions

The Company has elected the following additional practical expedients in applying Topic 606:

- ***Commission Expense***: We apply the practical expedient in ASC Topic 606 to expense costs as incurred for sales commissions when the period of benefit is one year or less. Most of our contracts are of a duration of one year or less, few, if any of the longer term contracts have commissions associated with them.

Transaction Price Allocated to Future Performance Obligations

- ASC 606 requires that the Company disclose the aggregate amount of transaction price that is allocated to performance obligations that have not yet been satisfied as of August 31, 2018. ASC 606 provides certain practical expedients that limit the requirement to disclose the aggregate amount of transaction price allocated to unsatisfied performance obligations.

The Company applied the practical expedient to not disclose the amount of transaction price allocated to unsatisfied performance obligations when the performance obligation is part of a contract that has an original expected duration of one year or less.

Cash and Cash Equivalents

For purposes of the statements of cash flows, the Company considers 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). Amortization of software development costs amounted to $339,073 and $285,310 for the three months ended November 30, 2018 and 2017, 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

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

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

Goodwill is tested for impairment at the reporting unit level, which is one level below or the same as an operating segment. As of November 30, 2018, the Company determined that it has three reporting units, Simulations Plus, Cognigen Corporation, and DILIsym Services, Inc. When testing goodwill for impairment, the Company first performs a qualitative assessment to determine whether it is necessary to perform step one of a two-step annual goodwill impairment test for each reporting unit. The Company is required to perform step one only if it concludes that it is more likely than not that a reporting unit's fair value is less than its carrying value. Should this be the case, the first step of the two-step process is to identify whether a potential impairment exists by comparing the estimated fair values of the Company's reporting units with their respective book values, including goodwill. If the estimated fair value of the reporting unit exceeds book value, goodwill is considered not to be impaired, and no additional steps are necessary. If, however, the fair value of the reporting unit is less than book value, then the second step is performed to determine if goodwill is impaired and to measure the amount of impairment loss, if any. The amount of the impairment loss is the excess of the carrying amount of the goodwill over its implied fair value. The estimate of implied fair value of goodwill is primarily based on an estimate of the discounted cash flows expected to result from that reporting unit, but may require valuations of certain internally generated and unrecognized intangible assets such as the Company's software, technology, patents, and trademarks. If the carrying amount of goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized in an amount equal to the excess.

As of November 30, 2018, the entire balance of goodwill was attributed to two of the Company's reporting units, Cognigen Corporation and DILIsym Services. Intangible assets subject to amortization are reviewed for impairment whenever events or circumstances indicate that the carrying amount of these assets may not be recoverable. There were no changes to goodwill, nor has the Company recognized any impairment charges, during the three months' periods ended November 30, 2018 and 2017.

Business Acquisitions

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

Company's consolidated financial statements as of the date of the acquisition.

Fair Value of Financial Instruments

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

Level Input:	**Input Definition:**
Level I	Inputs are unadjusted, quoted prices for identical assets or liabilities in active markets at the measurement date.
Level II	Inputs, other than quoted prices included in Level I, that are observable for the asset or liability through corroboration with market data at the measurement date.
Level III	Unobservable inputs that reflect management’s best estimate of what market participants would use in pricing the asset or liability at the measurement date.

For certain of our financial instruments, including accounts receivable, accounts payable, 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.

The following table summarizes fair value measurements at November 30, 2018 and August 31, 2018 for assets and liabilities measured at fair value on a recurring basis:

November 30, 2018:

	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	$9,352,238	$ –	$–	$9,352,238
Acquisition-related contingent consideration obligations	$–	$ –	$3,372,484	$3,372,484

August 31, 2018:

	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	$9,400,701	$ –	$–	$9,215,701
Acquisition-related contingent consideration obligations	$–	$ –	$4,890,940	$4,890,940

As of November 30, 2018 and August 31, 2018, the Company has a liability for contingent consideration related to its acquisition of the DILIsym Services, Inc. The fair value measurement of the contingent consideration obligations is determined using Level 3 inputs. The fair value of contingent consideration obligations is based on a discounted cash flow model using a probability-weighted income approach. These fair value measurements represent Level 3 measurements as they are based on significant inputs not observable in the market. Significant judgment is employed in determining the appropriateness of these assumptions as of the acquisition date and for each subsequent period. Accordingly, changes in assumptions could have a material impact on the amount of contingent consideration expense the Company records in any given period. Changes in the value of the contingent consideration obligations are recorded in the Company’s Consolidated Statement of Operations.

The following is a reconciliation of contingent consideration value.

Value at August 31, 2018	$4,890,940
Contingent consideration payments	(1,556,644)
Change in value of contingent consideration	38,188
Value at November 30, 2018	$3,372,484

Research and Development Costs

Research and development costs are charged to expense as incurred until technological feasibility has been established. These costs include salaries, laboratory experiment, and purchased software which was developed by other companies and incorporated into, or used in the development of, our final products.

Income Taxes

The Company accounts for income taxes in accordance with 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 three-month periods ended November 30, 2018 and 2017 was $1,875. Accumulated amortization as of November 30, 2018 and August 31, 2018 was $50,625 and $48,750, respectively.

On May 15, 2014, we entered into a termination and nonassertion agreement with TSRL, Inc., pursuant to which the parties agreed to terminate an exclusive software licensing agreement entered into between the parties in 1997. As a result, the company obtained a perpetual right to use certain source code and data, and TSRL relinquished any rights and claims to any GastroPlus products and to any claims to royalties or other payments under that 1997 agreement. We agreed to pay TSRL total consideration of $6,000,000, which is being amortized over 10 years under the straight-line method. Amortization expense for each of the three-month periods ended November 30, 2018 and 2017 was $150,000. Accumulated amortization as of November 30, 2018 and August 31, 2018 was $2,725,000 and $2,575,000, respectively.

On June 1, 2017, as part of the acquisition of DILIsym Services, Inc. the Company acquired certain developed technologies associated with the drug induced liver disease (DILI). These technologies were valued at $2,850,000 and are being amortized over 9 years under the straight-line method. Amortization expense for the three months ended November 30, 2018 and 2017 was $79,167 and is included in cost of revenues. Accumulated amortization as of November 30, 2018 and August 31, 2018 was $475,000 and $395,833, respectively.

In September 2018, we purchased certain intellectual property rights of Entelos Holding Company, a Delaware Corporation. The cost of $50,000 is being amortized over 10 years under the straight-line method. Amortization expense for the three-month period ended November 30, 2018 was $1,250. Accumulated amortization as of November 30, 2018 was $1,250.

Total amortization expense for intellectual property agreements for the three months ended November 30, 2018 and 2017 was $321,667 and $320,417, respectively. Accumulated amortization as of November 30, 2018 was $3,251,876 and $3,019,583 as of August 31, 2018.

Intangible assets

The following table summarizes those intangible assets as of November 30, 2018:

	Amortization Period	Acquisition Value	Accumulated Amortization	Net book value
Customer relationships-Cognigen	Straight line 8 years	$1,100,000	$ 584,375	$515,625
Trade Name-Cognigen	None	500,000	0	500,000
Covenants not to compete-Cognigen	Straight line 5 years	50,000	42,500	7,500
Covenants not to compete-DILIsym	Straight line 4 years	80,000	30,000	50,000
Trade Name-DILIsym	None	860,000	0	860,000
Customer relationships-DILIsym	Straight line 8 years	1,900,000	285,000	1,615,000
		$4,490,000	**$ 941,875**	**$3,548,125**

Amortization expense for each of the three month periods ended November 30, 2018 and 2017 was $89,375, respectively. According to policy in addition to normal amortization, these assets are tested for impairment as needed.

Earnings per Share

We report earnings per share in accordance with FASB ASC 260-10. Basic earnings per share is computed by dividing income available to common shareholders by the weighted-average number of common shares available. Diluted earnings per share is computed similar to basic earnings per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. The components of basic and diluted earnings per share for the three months ended November 30, 2018 and 2017 were as follows:

	Three months ended	
	11/30/2018	11/30/2017
Numerator:		
Net income attributable to common shareholders	$1,535,947	1,716,005
Denominator:		
Weighted-average number of common shares outstanding during the period	17,421,838	17,282,132
Dilutive effect of stock options	575,897	577,551
Common stock and common stock equivalents used for diluted earnings per share	17,997,735	17,859,683

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 $200,029 and $130,221 for the three months ended November 30, 2018 and 2017, respectively. This expense is included in the condensed consolidated statements of operations as Selling, General, and Administration (SG&A), and Research and Development expense.

Impairment of Long-lived Assets

The Company accounts for the impairment and disposition of long-lived assets in accordance with ASC 350, *"Intangibles – Goodwill and Other*" and ASC 360, *"Property and Equipment"*. Long-lived assets to be held and used are reviewed for events or changes in circumstances that indicate that their carrying value may not be recoverable. We measure recoverability by comparing the carrying amount of an asset to the expected future undiscounted net cash flows generated by the asset. If we determine that the asset may not be recoverable, or if the carrying amount of an asset exceeds its estimated future undiscounted cash flows, we recognize an impairment charge to the extent of the difference between the fair value and the asset's carrying amount. No impairment losses were recorded during the three months ended November 30, 2018 and 2017.

Recently Issued Accounting Pronouncements

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

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

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

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

In April 2016, the FASB issued AS 2016-10, Revenue from Contracts with Customers (Topic 606), which amends certain aspects of the Board's new revenue standard, ASU 2014-09, Revenue from Contracts with Customers. The standard should be adopted concurrently with adoption of ASU 2014-09 which is effective for annual and interim periods beginning after December 15, 2017.

NOTE 3. REVENUE RECOGNITION

The Company adopted Topic 606 effective September 1, 2018 using the modified retrospective method applying this guidance to all open contracts at the date of initial application, which resulted in an adjustment to retained earnings for the cumulative effect of applying this guidance. The most significant impact of Topic 606 on revenue to the Company

relates to the timing of revenue recognition for one of its payment contracts. Under 606 the revenues under the contract are being recognized as time is expended and costs are being expensed as incurred. Under ASC 605 revenues were recognized as invoiced and certain costs were capitalized as development.

We generate revenue primarily from the sale of software licenses and providing consulting services to the pharmaceutical industry for drug development.

The Company determines revenue recognition through the following steps:

i. Identification of the contract, or contracts, with a customer
ii. Identification of the performance obligations in the contract
iii. Determination of the transaction price
iv. Allocation of the transaction price to the performance obligations in the contract
v. Recognition of revenue when, or as, the Company satisfies a performance obligation

The Company accounts for a contract when it has approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of consideration is probable. Contracts generally have fixed pricing terms and are not subject to variable pricing. The Company considers the nature and significance of each specific performance obligation under a contract when allocating the proceeds under each contract. Accounting for contracts includes significant judgement in the estimation of estimated hours/cost to be incurred on consulting contracts, and the *di minimis* nature of the post sales costs associated with software sales.

Components of revenue

The following is a description of principal activities from which the Company generates revenue. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. Stand-alone selling prices are determined based on the prices at which the Company separately sells its services or goods.

Revenue Components	Typical payment terms
Software Revenues:	
Software revenues are generated primarily from sales of software licenses at the time the software is unlock and the term commences. The license period typically is one year or less. Along with the license a *di minimis* amount of customer support is provided to assist the customer with the software. Should the customer need more than a di minimis amount of support they can choose to enter in to a separate contract for additional training. Most software is installed on our customers servers and the Company has no control of the software once the sale is made.	Payments are generally due upon invoicing on a net 30 basis unless other payment terms are negotiated with the customer based on customer history. Typical industry standards apply.
For certain software arrangements the Company hosts the licenses on servers maintained by the Company, revenue for those arrangements are accounted as *Software as a Service* over the life of the contract. These arrangements are a small portion of software revenues of the Company.	
Consulting Contracts:	
Consulting services provided to our customers are generally recognized over time as the contracts are performed and the services are rendered. The company measures its consulting revenue based on time expended compared to total hours to complete a project. The Company believes the methods chosen for its contract revenue best depicts the transfer of benefits to the customer under the contracts.	Payment terms vary, depending on the size of the contract, credit history and history with the client and deliverables within the contract.

Consortium Member Based Services:

The performance obligation is recognized on a time elapsed basis, by month, for which the services are provided, as the Company transfers control evenly over the contractual period.	Payment is due at the beginning of the period, generally on a net 30 or 60 basis.

Remaining performance obligations that do not fall under the expedients require the Company to perform various consulting and software development services and consortium memberships of approximately $3,300,000. It is anticipated these revenues will be recognized within the next two and ½ years.

Contract liabilities

During the period ended November 30, 2018 the Company recognized $433,500 of revenue that was included in contract liabilities as of August 31, 2018.

Disaggregation of Revenues

Disaggregation of Revenues:	Three Months Ended November 30, 2018
Software licenses	
Point in time	$3,757,330
Over time	364,058
Consulting services	
Over time	3,414,515
Total Revenue	$7,535,903

The following table summarizes the adjustments made to accounts on the condensed consolidated balance sheet as of September 1, 2018 as a result of applying the modified retrospective method to adopt ASC Topic 606:

	As Reported August 31, 2018	**Adjustments to reflect the adoption of ASC Topic 606**	As Adjusted September 1, 2018
Capitalized Software, net	$5,152,594	$ (629,100)	$4,523,494
Deferred revenue	381,928	294,825	676,753
Deferred income taxes, net	3,195,139	(230,981)	2,964,158
Retained Earnings	$18,461,540	$ (692,944)	$17,768,596

The following tables present the amount by which each condensed consolidated financial statement line item is affected as of and for the three months ended November 30, 2018 by ASC Topic 606:

	Three Months Ended November 30, 2018		
	As Reported	Balances Without the adoption of ASC Topic 606	Effect of Change
Revenues	$7,535,903	$7,479,081	$56,822
Cost of revenues	2,200,371	2,145,266	55,105
Gross profit	5,335,532	5,333,815	1,717
Income from operations	2,086,745	2,085,028	1,717
Income before provision for income taxes	2,021,618	2,019,901	1,717
Provision for income taxes	(485,671)	(471,466)	(14,205)
Net Income	$1,535,947	1,548,435	$(12,488)
Earnings per share-Diluted	$0.09	$0.09	$0.00
Weighted-average common shares outstanding	$17,997,735	$17,997,735	$–

	Three Months Ended November 30, 2018		
	As Reported	Balances Without the adoption of ASC Topic 606	Effect of Change
Cash Flows From Operating Activities:			
Net loss	$ 1,535,947	$ 1,548,435	$ (12,488)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation and amortization	694,789	729,824	(35,035)
Changes in operating assets and liabilities:			
Deferred revenue	(222,769)	(279,591)	56,822
Net cash provided by operating activities	2,611,721	2,553,182	58,539
Cash flows used in investing activities			
Capitalized computer software development costs	$ (364,664)	$ (454,804)	$ 90,140

NOTE 4: Property and Equipment

Property and equipment as of November 30, 2018 consisted of the following:

Equipment	$741,984
Computer equipment	287,089
Furniture and fixtures	148,544
Leasehold improvements	110,165
Sub total	1,287,783
Less: Accumulated depreciation and amortization	(985,352)
Net Book Value	$302,431

NOTE 5: CONTRACTS PAYABLE

DILIsym Acquisition Liabilities:

On June 1, 2017, the Company acquired DILIsym Services, Inc. The agreement provided for a working capital adjustment, an eighteen-month $1,000,000 holdback provision against certain representations and warranties, and an Earn-out agreement of up to an additional $5,000,000 in Earn-out payments based on earnings over three years. The Earn-out liability has been recorded at an estimated fair value. Payments under the Earn-out liability started in FY 2019. The first payment of $1,566,644 was made in September 2018, the holdback payment was made in December 2018. It is estimated that approximately 40% of the original Earn-out liability will be paid in the second year and the remainder of the Earn-out will be paid in the following year.

As of November 30, 2018 and August, 31, 2018 the following liabilities have been recorded:

	November 30, 2018	August 31, 2018
Working Capital Liability	$–	$–
Holdback Liability	1,000,000	1,000,000
Earn-out Liability	3,372,484	4,890,940
Sub Total	$4,372,484	$5,890,940
Less: Current Portion	2,750,000	2,556,644
Long-Term	$1,622,484	$3,334,296

NOTE 6: COMMITMENTS AND CONTINGENCIES

Leases

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

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

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

Rent expense, including common area maintenance fees for the three months ended November 30, 2018, and 2017 was $144,012, and $135,877, respectively.

Employment Agreements

In the normal course of business, the Company has entered into employment agreements with certain of its key management personnel that may require compensation payments upon termination.

License Agreement

The Company has a royalty agreement with Dassault Systèmes Americas Corp. 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. Under this agreement, we pay a royalty

of 25% of revenue derived from the sale of the Metabolism/Metabolite module. We incurred royalty expense of $38,109 and $35,897, respectively, for the three months ended November 30, 2018 and 2017, 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. Interest and penalties totaled $-0- for fiscal year 2018 We file income tax returns with the IRS and various state jurisdictions and India. Our federal income tax returns for fiscal year 2012 thru 2013 and 2015 are open for audit, and our state tax returns for fiscal year 2011 through 2015 remain open for audit. In addition, our California tax return for the fiscal year 2007 and fiscal year 2008 remains open with regard to R&D tax credits as a result of a previous audit for which we received a letter from the California Franchise Tax Board stating that an audit will not be conducted for those years at this time; however it may be subject to future audit.

Our review of prior year tax positions using the criteria and provisions presented in guidance issued by FASB did not result in a material impact on our financial position or results of operations.

Litigation

From time to time, we may be involved in routine legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of our business. Litigation can be expensive and disruptive to normal business operations. Moreover, the results of legal proceedings, particularly complex legal proceedings, cannot be predicted with any certainty.

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

NOTE 7: SHAREHOLDERS' EQUITY

Dividend

The Company's Board of Directors declared cash dividends during fiscal years 2019 and 2018. The details of the dividends paid are in the following tables:

FY2019

Record Date	Distribution Date	Number of Shares Outstanding on Record Date	Dividend per Share	Total Amount
11/1/2018	11/08/2018	17,417,875	$ 0.06	$ 1,045,073
Total				**$ 1,045,073**

FY2018

Record Date	Distribution Date	Number of Shares Outstanding on Record Date	Dividend per Share	Total Amount
11/13/2017	11/20/2017	17,284,792	$ 0.06	$ 1,037,088
1/26/2018	2/2/2018	17,317,752	$ 0.06	$ 1,039,065
4/25/2018	5/2/2018	17,354,005	$ 0.06	$ 1,041,240
7/26/2018	8/2/2018	17,405,775	$ 0.06	$ 1,044,347
Total				**$ 4,161,740**

Stock Option Plan

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

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

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

As of November 30, 2018, employees and directors hold Qualified Incentive Stock Options and Non-Qualified Stock Options to purchase 1,080,846 shares of common stock at exercise prices ranging from $1.00 to $23.75.

The following table summarizes information about stock options:

Transactions in FY18	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life
Outstanding, August 31, 2018	1,134,976	$ 9.44	7.31
Granted	12,000	$ 22.24	
Exercised	(41,103)	$ 9.15	
Cancelled/Forfeited	(25,027)	$ 9.89	
Outstanding, November 30, 2018	**1,080,846**	**$ 9.58**	**7.04**
Exercisable, November 30, 2018	454,006	$ 7.79	6.20

The weighted-average remaining contractual life of options outstanding issued under the Plan, both Qualified ISO and Non-Qualified SO, was 7.04 years at November 30, 2018. The exercise prices for the options outstanding at November 30, 2018 ranged from $1.00 to $23.75, 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	$4.00	36,000	.35 years	$ 1.00	36,000	.35 years	$ 1.00
$4.01	$8.00	267,890	5.76 years	$ 6.85	207,400	5.77 years	$ 6.85
$8.01	$12.00	704,840	7.76 years	$ 9.87	206,440	7.61 years	$ 9.79
$12.01	$16.00	12,916	8.72 years	$ 14.44	4,166	8.73 years	$ 14.46
$16.01	$20.00	7,200	3.96 years	$ 17.71	0	–	$ –
$20.01	$23.75	52,000	8.51 years	$ 23.40	–	–	–
		1,080,846	**7.04 years**	**$ 9.58**	**454,006**	**6.20 years**	**$ 7.79**

During the period ended November 30, 2018 the company issues 2,222 shares of stock to non-management directors of the Company valued at $44,904 as compensation for services rendered to the Company.

NOTE 8: CONCENTRATIONS AND UNCERTAINTIES

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash, cash equivalents, and trade accounts receivable. The Company holds cash and cash equivalents at banks located in California and North Carolina with balances that often exceed FDIC insured limits. Historically, the Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk on cash and cash equivalents. However, considering the current banking environment, the Company is investigating alternative ways to minimize its exposure to such risks. While the Company may be exposed to credit losses due to the nonperformance of its counterparties, the Company does not expect the settlement of these transactions to have a material effect on its results of operations, cash flows, or financial condition. The Company maintains cash at financial institutions that may, at times, exceed federally insured limits. At November 30, 2018 the Company had cash and cash equivalents exceeding insured limits by $8,273,000.

Revenue concentration shows that international sales accounted for 35% and 31.8% of net sales for the three months ended November 30, 2018 and 2017, respectively. Four customers accounted for 13%, 9%, 7%, and 6% (a dealer account in Japan representing various customers) of net sales during the three months ended November 30, 2018. Four customers accounted for 7%, 7% (a dealer account in Japan representing various customers), 6% and 6% of net sales during the three months ended November 30, 2017.

Accounts receivable concentration shows that six customers comprised 15%, 7%, 7% (a dealer account in Japan representing various customers), 6%, and 6% of accounts receivable at November 30, 2018. Accounts receivable concentration shows that six customers comprised 18%, 8%, 8% (a dealer account in Japan representing various customers), 7%, 6%, and 5% of accounts receivable at November 30, 2017.

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 ended November 30, 2018 and 2017 (in thousands, because of rounding numbers may not foot):

November 30, 2018

	Lancaster	Buffalo	North Carolina*	Eliminations	Total
Net revenues	$ 4,365	$ 2,065	$ 1,106	$ –	$ 7,536
Income (loss) from operations	$ 1,607	$ 303	$ 175	$ –	$ 2,085
Total assets	$ 36,889	$ 8,635	$ 14,126	$ (17,702)	$ 41,948
Capital expenditures	$ 1	$ –	$ –	$ –	$ 1
Capitalized software costs	$ 290	$ 30	$ 45	$ –	$ 365
Depreciation and amortization	$ 462	$ 91	$ 142	$ –	$ 695

*Acquired June 1, 2017

November 30, 2017

	Lancaster	Buffalo	North Carolina*	Eliminations	Total
Net revenues	$ 4,042	$ 1,913	$ 1,114	$ –	$ 7,069
Income (loss) from operations	$ 1,641	$ 508	$ 415	$ –	$ 2,564
Total assets	$ 33,033	$ 10,429	$ 13,990	$ (17,702)	$ 39,750
Capital expenditures	$ 25	$ 18	$ 5	$ –	$ 48
Capitalized software costs	$ 283	$ 159	$ 66	$ –	$ 507
Depreciation and amortization	$ 414	$ 87	$ 137	$ –	$ 638

*Acquired June 1, 2017

In addition, the Company allocates revenues to geographic areas based on the locations of its customers. Geographical revenues for the three months ended November 30, 2018 and 2017 were as follows (in thousands, because of rounding numbers may not foot):

Three months ended November 30, 2018

	North America	Europe	Asia	South America	Total
Lancaster	$ 2,111	$ 947	$ 1,306	$ 1	$ 4,365
Buffalo	2,065	–	–	–	2,065
North Carolina	745	51	310	–	1,106
Total	$ 4,911	$ 998	$ 1,616	$ 1	$ 7,536

Three months ended November 30, 2017

	North America	Europe	Asia	South America	Total
Lancaster	$ 1,816	$ 1,089	$ 1,133	$ 4	$ 4,042
Buffalo	1,913	–	–	–	1,913
North Carolina	811	12	291	–	1,114
Total	$ 4,540	$ 1,101	$ 1,424	$ 4	$ 7,069

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 $86,940 and $71,381 for the three months ended November 30, 2018 and 2017, respectively.

NOTE 11- SUBSEQUENT EVENT

On January 8, 2019, our Board of Directors declared a quarterly cash dividend of $0.06 per share to our shareholders. The dividend will be distributed on Friday February 1, 2019, for shareholders of record as of Friday January 25, 2019.

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,” “cou “would,” “projects,” “continues,” “estimates” or similar expressions. Forward-looking statements are not guarantees of future performance and actual results could differ materially from those indicated by the forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our or our industry’s actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by the forward-looking statements.

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

Among the important factors that could cause actual results to differ materially from those indicated by forward-looking statements are the risks and uncertainties described under “Risk Factors” in our Annual Report and elsewhere in this document and in our other filings with the SEC.

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

General

BUSINESS

OVERVIEW

Simulations Plus, Inc., incorporated in 1996, is a premier developer of groundbreaking drug discovery and development software for mechanistic modeling and simulation, and for machine-learning-based prediction of properties of molecules solely from their structure. Our pharmaceutical/chemistry software is licensed to major pharmaceutical, biotechnology, agrochemical, cosmetics, and food industry companies and to regulatory agencies worldwide for use in the conduct of industry-based research. We also provide consulting services ranging from early drug discovery through preclinical and clinical trial data analysis and for submissions to regulatory agencies. Simulations Plus is headquartered in Southern California, with offices in Buffalo, New York, and Research Triangle Park, North Carolina, and its common stock trades on the Nasdaq Capital Market under the symbol “SLP.”

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

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

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

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

PRODUCTS

General

We currently offer ten software products for pharmaceutical research and development: five simulation programs that provide time-dependent results based on solving large sets of differential equations: GastroPlus®; DDDPlus™; MembranePlus™; DILIsym®; and NAFLDsym™; three programs that are based on predicting and analyzing static (not time-dependent) properties of chemicals: ADMET Predictor®; MedChem Designer™; and MedChem Studio™ (the combination of ADMET Predictor, MedChem Designer, and MedChem Studio is called our ADMET Design Suite™); a

program which is designed for rapid clinical trial data analysis and regulatory submissions called PKPlus™; and a program called KIWI™ from our Cognigen division that provides an integrated platform for data analysis and reporting through our proprietary secure cloud.

GastroPlus®

Our flagship product, originally introduced in 1998, and currently our largest single source of software revenue, is GastroPlus. GastroPlus mechanistically simulates the absorption, pharmacokinetics, pharmacodynamics, and drug-drug interactions of compounds administered to humans and animals and is currently the most widely used commercial software of its type by pharmaceutical companies, the U.S. Food and Drug Administration (FDA), the U.S. National Institutes of Health (NIH), and other government agencies in the U.S. and other countries.

Because of the widespread use of GastroPlus, we were the only non-European company invited to join the European Innovative Medicines Initiative (IMI) program for Oral Bioavailability Tools (OrBiTo). OrBiTo was an international collaboration among 27 industry, academic, and government organizations working in the area of oral absorption of pharmaceutical products. Because we are outside of the European Union, our participation in this project was at our own expense, while other members were compensated for their work; however, we were a full member with access to all of the data and discussions of all other members. We believe our investment to participate in this initiative enabled us to benefit from, and to contribute to, advancing the prediction of human oral bioavailability from preclinical data, and ensured that we are well-known to member pharmaceutical companies and regulatory agencies.

In September 2014, we entered into a research collaboration agreement (RCA) with the FDA to enhance the Ocular Compartmental Absorption and Transit (OCAT™) model within the Additional Dosing Routes Module of GastroPlus. The objective of this agreement was to provide a tool for generic companies and the FDA to assess the likely bioequivalence of generic drug formulations dosed to the eye. Under this RCA, we received up to $200,000 per year. This RCA could be renewed for up to a total of three years based on the progress achieved during the project. After a successful second year, the RCA was extended for two additional years in September 2016, with primary tasks completed in September 2018. Additional functionality was further requested by the FDA, and a new funded contract was awarded for the 2018-19 period.

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

In September 2018, we were pleased to announce that we were awarded another funded RCA by the FDA to integrate drug product quality attributes into the mechanistic TCAT model in GastroPlus. This grant award, for $250,000 per year for up to two years, will focus on the incorporation of drug product quality attributes into dermal physiologically-based pharmacokinetic (PBPK) models developed for dermatological topical dosage forms and transdermal delivery systems.

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

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

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

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

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

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

DDDPlus™

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

Version 6.0 of DDDPlus, released in December 2018, offers a series of new capabilities, including:

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

MembranePlus™

Similar to DDDPlus, MembranePlus mechanistically simulates laboratory experiments, but in this case, the experiments are for measuring permeability of drug-like molecules through various membranes, including several different standard cell cultures (Caco-2, MDCK), as well as artificially formulated membranes (PAMPA). The value of such simulations derives from the fact that when the permeabilities of the same molecules are measured in different laboratories using (supposedly) the same experimental conditions, the results are often significantly different. These differences are caused by a complex interplay of factors in how the experiment was set up and run. MembranePlus simulates these experiments with their specific experimental details, and this enables scientists to better interpret how results from specific experimental protocols can be used to predict permeability in human and animals, which is the ultimate goal.

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

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

PKPlus™

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

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

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

ADMET Predictor®

ADMET (Absorption, Distribution, Metabolism, Excretion, and Toxicity) Predictor is a chemistry-based computer program that takes molecular structures (i.e., drawings of molecules represented in various formats) as inputs and predicts approximately 150 different properties for them at an average rate of over 100,000 compounds per hour on a modern laptop computer. This capability allows chemists to generate estimates for a large number of important molecular properties without the need to synthesize and test the molecules, as well as to generate estimates of unknown properties for molecules that have been synthesized, but for which only a limited number of experimental properties have been measured. Thus, a chemist can assess the likely success of a large number of existing molecules in a company's chemical library, as well as molecules that have never been made, by providing only their molecular structures, either by drawing them using a tool such as our MedChem Designer software, or by automatically generating large numbers of molecules using various computer algorithms, including those embedded in our MedChem Studio software.

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

The optional ADMET Modeler™ Module in ADMET Predictor enables scientists to use their own experimental data to quickly create proprietary high-quality predictive models using the same powerful artificial intelligence (AI) engine we use to build our top-ranked property predictions. Pharmaceutical companies expend substantial time and money conducting a wide variety of experiments on new molecules each year, generating large databases of experimental data. Using this proprietary data to build predictive models can provide a second return on their investment; however, model building has traditionally been a difficult and tedious activity performed by specialists. The automation in

ADMET Modeler makes it easy for a scientist to create very powerful machine-learning/AI models with minimal training.

Version 9.0 was released in June 2018, adding:

- Additional pharmacokinetic (PK) endpoint predictions included with the High-Throughput Pharmacokinetics (HTPK) Simulation Module
- New artificial intelligence (machine-learning) models to predict major clearance mechanisms
- Novel DELTA Model™ approach extends model coverage space adding client data through the ADMET Modeler Module
- Multi-class classification models can now be built using our advanced artificial neural network ensemble (ANNE) methodology
- Intuitive graphical display of Biopharmaceutical Classification System (BCS) and Developability Classification System (DCS)
- Rebuilt most classification models to improve their confidence estimates
- New functionality for easily generating and visualizing fingerprints within the MedChem Studio Module

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

Potential new markets for artificial intelligence (machine learning)

We are currently investigating applications of our sophisticated artificial intelligence (machine-learning) engine outside of our normal pharmaceutical markets. To date, we have conducted several proof-of-concept studies including: (1) predicting missile aerodynamic force and moment coefficients as a function of missile geometry, Mach number, and angle of attack, (2) classifying/identifying missiles and other objects from radar tracking data, (3) mapping jet engine compressor performance to predict when maintenance might be required, and (4) classifying patients as healthy or experiencing some disease state or genetic disorder evidenced by magnetic resonance imaging (MRI) of the brain. Other potential applications for this modeling engine have also been identified; however, our focus to date has been primarily in these areas.

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

MedChem Designer™

MedChem Designer was initially a molecule-drawing program, or "sketcher", but now has capabilities far exceeding those of other molecule-drawing programs because of its integration with both MedChem Studio and ADMET Predictor. We provide MedChem Designer for free because we believe that in the long run it will help to increase demand for ADMET Predictor and MedChem Studio, and because most other existing molecule-drawing programs are also provided for free. Our free version includes a small set of ADMET Predictor's best-in-class property predictions, allowing the chemist to modify molecular structures and then see a few key properties very quickly. With a paid ADMET Predictor license, the chemist would see the entire approximately 150 predictions that are available. Over 26,500 copies of MedChem Designer have been downloaded by scientists around the world to date.

When used with a license for ADMET Predictor, MedChem Designer becomes a *de novo* molecule design tool. With it, a researcher can draw one or more molecular structures, then click on the ADMET Predictor icon and have approximately 150 properties for each structure calculated in seconds, including our proprietary ADMET Risk™ index. Researchers can also click on an icon to generate the likely metabolites of a molecule and then predict all of the properties of those metabolites from ADMET Predictor, including each of their ADMET Risk scores. This is

important because a metabolite of a molecule can be therapeutically beneficial (or harmful) even though the parent molecule is not.

Our proprietary ADMET Risk score provides a single number that tells the chemist how many default threshold values for various predicted properties were crossed (or violated) by each structure. Thus, in a single number, the chemist can instantly compare the effects of different structural changes in many dimensions. The ideal score is zero; however, a low score greater than zero might be acceptable, depending on what property(s) caused the points to be assigned. If the number is too high (greater than 7), the molecule is not likely to be successful as a drug. The default rules can be modified and new rules can be added by the user to include any desired rule set based on any combination of calculated molecular descriptors, predicted properties, and user inputs. As chemists attempt to modify structures to improve one property, they often cause others to become unacceptable. Without ADMET Risk, the chemist would have to individually examine many key properties for each new molecule (and its metabolites) to determine whether any of them became unacceptable as a result of changing the structure.

MedChem Studio™

The MedChem Studio Module in ADMET Predictor 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.

While MedChem Designer can be used to refine a small number of molecules, the MedChem Studio Module can be used to create and screen very large numbers of molecules down to a few promising lead candidates. MedChem Studio has features that enable it to generate new molecular structures using a variety of *de novo* design methods. When MedChem Studio is used with ADMET Predictor and MedChem Designer (the combination of which we refer to as our ADMET Design Suite), we believe the programs provide an unmatched capability for chemists to search through large libraries of compounds that have undergone high-throughput screening experiments to find the most promising classes (groups of molecules with a large common part of their structures) and molecules that are active against a particular target. In addition, MedChem Studio can take an interesting (but not acceptable) molecule and, using a variety of design algorithms, quickly generate many thousands to millions of high quality analogs (similar new molecules). These molecules can then be screened using ADMET Predictor to find molecules that are predicted to be both active against the target and acceptable in a variety of ADMET properties. We demonstrated the power of the ADMET Design Suite during two NCE (new chemical entity) projects wherein we designed lead molecules to inhibit the growth of the plasmodium falciparum malaria parasite in one study, and lead molecules that were able to inhibit two targets at the same time: COX-1 and COX-2. In each case, we announced ahead of time that we were attempting to do this, and we reported the results when the projects were complete. Every molecule we designed and had synthesized hit their targets in both projects, clearly demonstrating the power of the ADMET Design Suite.

KIWI™

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

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

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

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

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

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

DILIsym

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

Version 8A of the DILIsym software was released in January 2019. This version is again delivered as a secure executable that incorporates new proprietary code enabling tighter integration with our GastroPlus PBPK software. Securing the code is necessary to ensure that results are consistent across all users to assure regulatory agencies that the calculated results are from a validated version. Open source programs are subject to modification by the user and so each use could have a different set of calculations, so validation would not be assured. In addition, a number of important new capabilities were added:

- 10 New validation compounds
- New Cholestatic liver injury mechanism
- New Oxidative stress (ROS) NRF2 adaptation response framework
- New Human SimPops with variability in bilirubin processing pathways
- New Liver injury biomarker GLDH
- Live DILIsym documentation website updated with new training resources

Plus much more……

NAFLDsym

Where DILIsym is used to investigate the likelihood that a known drug molecule would cause injury to the liver, NAFLDsym is concerned with a liver that is already diseased by excess fat and investigates the likelihood that various molecules might provide beneficial therapeutic benefits to treat or cure the disease. DILIsym can be considered a “shrink wrap” software product, usable across many companies and drug development projects. NAFLDsym, on the other hand, requires modification for each of a number of different mechanisms of action that potential new drug

compounds could use to treat the disease, and so is a customized tool used in consulting projects for each new client project. NAFLDsym version 2A will be released for licensing and consulting use in Q1 of 2019. The software now includes the three most important components of NAFLD/NASH: steatosis, inflammation, and fibrosis.

RENAsym

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

Contract Research and Consulting Services

Our scientists and engineers have expertise in drug absorption via various dosing routes (oral, intravenous, subcutaneous, intramuscular, ocular, nasal/pulmonary, and dermal), pharmacokinetics, pharmacodynamics, and drug-drug interactions. They have attended over 200 scientific meetings worldwide in the past four years, often speaking and presenting. We conduct contracted consulting studies for large customers (including many of the top twenty pharmaceutical companies) who have particularly difficult problems and who recognize our expertise in solving them, as well as for smaller customers who prefer to have studies run by our scientists rather than to license our software and train someone to use it. The demand for our consulting services has been steadily increasing, and we have expanded our consulting teams to meet the increased workload.

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

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

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

PRODUCT DEVELOPMENT

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

To date, we have developed products internally, sometimes also licensing or acquiring products, or portions of products, from third parties. These arrangements sometimes require that we pay royalties to third parties. We intend to continue to license or otherwise acquire technology or products from third parties when it makes business sense to do so. We currently have one license agreement, with Dassault Systèmes Americas Corp. (formerly known as Accelrys, Inc.), a San Diego division of Dassault Systemes in France, pursuant to which a small royalty is paid to Dassault Systèmes Americas Corp. from revenues on each license for the Metabolism Module in ADMET Predictor. This license agreement continues in perpetuity and either party has the right to terminate it.

In 1997 we entered into an exclusive software licensing agreement with TSRL, Inc. (Therapeutic Systems Research Laboratories) pursuant to which TSRL licensed certain software technology and databases to us, and we paid royalties to TSRL. On May 15, 2014, we and TSRL entered into a termination and nonassertion agreement pursuant to which the parties agreed to terminate the 1997 exclusive software licensing agreement. As a result, the Company obtained a perpetual right to use certain source code and data, and TSRL relinquished any rights and claims to any GastroPlus products and to any claims to royalties or other payments under that agreement, and we agreed to pay TSRL total consideration of $6,000,000. All payments were made as of April 2017. The total consideration is being amortized at a constant rate of $150,000 per quarter until it is completely amortized, after which no further expense will be incurred. To date, this has resulted in expense savings over $1,300,000 compared to the royalty payments that would have been paid to TSRL if paid consistent with past practices.

MARKETING AND DISTRIBUTION

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

We market our pharmaceutical software and consulting services through attendance and presentations at scientific meetings, exhibits at trade shows, seminars at pharmaceutical companies and government agencies, through our website, and using various communication channels to our database of prospects and customers. At various scientific meetings around the world each year there are numerous presentations and posters presented in which the reported research was performed using our software. Many of these presentations are from industry and FDA scientists; some are from our staff. In addition, more than 100 peer-reviewed scientific journal articles, posters, and podium presentations are typically published each year using our software, mostly by our customers, further supporting its use in a wide range of preclinical and clinical studies.

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

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

PRODUCTION

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

COMPETITION

In our pharmaceutical software and services business, we compete against a number of established companies that provide screening, testing and research services, and products that are not based on simulation software. There are also software companies whose products do not compete directly with, but are sometimes closely related to, ours. Our competitors in this field include some companies with financial, personnel, research, and marketing resources that are larger than ours. Our flagship product, GastroPlus, is the most widely used commercial PBPK modeling platform and has one significant competitor; others could be developed over time, but with the high barrier to entry, it would be difficult to validate new software to levels required to support regulatory submissions. Our PKPlus software product will compete with one major and a few minor software programs. MedChem Studio, MedChem Designer, and ADMET Predictor/ADMET Modeler operate in a more competitive environment. Several other companies presently offer simulation or modeling software, or simulation-software-based services, to the pharmaceutical industry. We believe DILIsym and NAFLDsym enjoy a unique market position, with no significant competition.

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

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

We believe the key factors in our ability to successfully compete in this field are our ability to: (1) continue to invest in research and development, and develop and support industry-leading simulation and modeling software and related products and services to effectively predict activities and ADMET-related behaviors of new drug-like compounds, (2) design new molecules with acceptable activity and ADMET properties, (3) develop and maintain a proprietary database of results of physical experiments that serve as a basis for simulated studies and empirical models, (4) continue to attract and retain a highly skilled scientific and engineering team, (5) aggressively promote our products and services to our global market, and (6) develop and maintain relationships with research and development departments of pharmaceutical companies, universities, and government agencies.

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

Results of Operations

Comparison of Three Months Ended November 30, 2018 and 2017.

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			
	11/30/18		11/30/17	
Net revenues	$7,536	100.0%	$7,069	100.0%
Cost of revenues	2,200	29.2	1,736	24.6
Gross profit	5,336	70.8	5,333	75.4
Selling, general and administrative	2,719	36.1	2,409	34.1
Research and development	530	7.0	361	5.1
Total operating expenses	3,249	43.1	2,769	39.2
Income from operations	2,087	27.7	2,564	36.3
Other income	(65)	(0.9)	(47)	(0.7)
Income from operations before taxes	2,020	27.0	2,517	35.6
(Provision for) income taxes	(486)	(6.4)	(801)	(11.3)
Net income	$1,536	20.4%	$1,716	24.3%

Net Revenues

Consolidated net revenues increased by 5.8% or $467,000 million to $7.54 million in the first fiscal quarter of Fiscal Year 2019 (“1QFY19”) from $7.07 million in the first fiscal quarter of Fiscal Year 2018 (“1QFY18”). Changes by division are as follows:

·Lancaster: $324,000 increase, representing a 8.0% increase to $4.37 million

·Buffalo (Cognigen): $151,000 increase, representing an 7.9% increase to $2.01million

·North Carolina (DILIsym): recorded revenues of $1.11 million, the same as the prior year

Consolidated software and software-related sales increased $365,000 or 9.7%, while consolidated consulting and analytical study revenues increased $46,000 or 3.1% over 1QFY18.

Cost of Revenues

Consolidated cost of revenues increased by $465,000, or 26.8%, in 1QFY19 to $2.20 million from $1.74 million in 1QFY18. Labor-related cost accounted for $310,000 of this increase, a combination of increased labor count, salary and benefit increases. Other significant increases in cost of revenues included $80,000 of direct contract expenses paid mostly for testing at DILIsym, as well as an additional $54,000 of software amortization expense.

Cost of Revenues as a percentage of revenue increased by 4.5% in 1QFY19 to 29.2% as compared to 24.7% in 1QFY18.

Gross Profit

Consolidated gross margin was relatively unchanged at $5.34 million in 1QFY19 compared $5.34 million in 1QFY18. The Lancaster division gross margin showed an increase of $206,000 or 6%, with a gross margin percentage of 82.4% for the quarter. The Buffalo Division Gross margin decreased $112,000 or 9.3%, with a gross margin percentage of 53.1% for the quarter. The North Carolina Division gross margin decreased $91,000 or 11.5% with a gross margin percentage of 63.5% for the quarter.

Overall gross margin decrease by 4.1% to 70.8% in 1QFY19 from 75.4% in 1QFY18.

Selling, General and Administrative Expenses

Selling, general, and administrative (SG&A) expenses increased $311,000, or 12.9% to $2.72 million in 1QFY19 from $2.41 million in 1QFY18. As a percent of revenues, SG&A was 36.1% for 1QFY19, compared to 34.1% in 1QFY18.

The major increases in SG&A expense were:

- G&A Salaries and Wages increased by $138,000; this increase is a combination of increased stock compensation costs of $22,000, increased costs associated with the new CEO, annual salary increases and increased head count in Lancaster and Buffalo, as well as a higher percentage of G&A allocation from scientific personnel.
- Software licenses: $29,000
- 401k expense: $16,000
- Insurance Expense $26,000; mostly health-related medical costs due to cost increased and higher employee counts,
- Payroll tax expense increased $41,000
- Commission expense: $33,000

The major decreases in SG&A expense were:

- Trade show expenses decreased $39,000

Research and Development

Total research and development cost increased $168,000 in 1QFY19 compared to 1QFY18. In 1QFY19 we incurred approximately $984,000 of research and development costs, of this amount, $455,000 was capitalized and $530,000 was expensed. In 1QFY18 we incurred approximately $868,000 of research and development costs, of this amount, $507,000 was capitalized and $361,000 was expensed.

Other income (expense)

Other income was an expense of $65,000 compared to expense of $47,000 in 1QFY18, a decrease of $18,000. Foreign currency exchange accounted for $17,000 of the change.

Provision for Income Taxes

The provision for income taxes was $486,000 for 1QFY19 compared to $801,000 for 1QFY18. Our effective tax rate decreased 7.8% to 24.0% in 1QFY19 from 31.8% in 1QFY18. The increase is a resulted mainly from the change in rates due to the new federal tax legislation passed in 2018.

Net Income

Net income decreased by $180,000, or 10.5%, in 1QFY19 to $1.54 million from $1.72 million in 1QFY18. Net earnings from our Lancaster division were up $41,000 or 3.7% to $1.15 million in 1QFY19. Net earnings for our Buffalo division were down $102,000 or 30.9% to $229,000 in 1QFY19. DILIsym (No. Carolina) net earnings decreased $139,000 or 51.2%.

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 ten fiscal years. We believe that our existing capital and anticipated funds from operations will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for the foreseeable future. Thereafter, if cash generated from operations is insufficient to satisfy our capital requirements, we may open a revolving line of credit with a bank, or we may have to sell additional equity or debt securities or obtain expanded credit facilities. In the event such financing is needed in the future, there can be no assurance that such financing will be available to us, or, if available, that it will be in amounts and on terms acceptable to us. If cash flows from operations became insufficient to continue operations at the current level, and if no additional financing was obtained, then management would restructure the Company in a way to preserve its pharmaceutical business while maintaining expenses within operating cash flows.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

As of November 30, 2018 and August 31, 2018, we had cash and cash equivalents of $9.35 million and $9.40 million, respectively. We do not hold any investments that are exposed to market risk related to changes in interest rates, which could adversely affect the value of our assets and liabilities, and we do not hold any instruments for trading purposes and investment. Some of our cash and cash equivalents are held in money market accounts; however, they are not exposed to market rate risk.

In the three months ended November 30, 2018 and 2017, we sold $809,000 and $670,000, respectively of software through representatives in certain Asian markets in local currencies. As a result, our financial position, results of operations, and cash flows can be affected by fluctuations in foreign currency exchange rates, particularly fluctuations in the yen and RMB exchange rates. These transactions give rise to receivables that are denominated in currencies other than the entity's functional currency. The value of these receivables are subject to changes because the receivables may become worth more or less due to changes in currency exchange rates. The majority of our software license agreements are denominated in U.S. dollars. We record foreign gains and losses as they are realized. We mitigate our risk from foreign currency fluctuations by adjusting prices in our foreign markets on a periodic basis. We base these changes on market conditions while working closely with our representatives. We do not hedge currencies or enter into derivative contracts.

Item 4. Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of November 30, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, management concluded as of November 30, 2018, that our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Please carefully consider the information set forth in this Quarterly Report on Form 10-Q and the risk factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended August 31, 2018, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K, as well as other risks and uncertainties, could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price of shares of our Common Stock. Additional risks not currently known or currently material to us may also harm our business.

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

35

Item 6. Exhibits

EXHIBIT NUMBER	DESCRIPTION
2.1 (4)^	Agreement and Plan of Merger, dated July 23, 2014, by and among the Company, Cognigen Corporation and the other parties thereto.
3.1 (2)	Articles of Incorporation of the Company.
3.2 (2)	Amended and Restated Bylaws of the Company.
4.1 (1)	Form of Common Stock Certificate.
4.2 (1)	Share Exchange Agreement.
10.1 (1) (†)	The Company's 1996 Stock Option Plan and forms of agreements relating thereto.
10.2 (3) (†)	The Company's 2007 Stock Option Plan, as amended.
10.3 (10)	Second Amendment to Lease by and between the Company and Crest Development LLC, dated as of May 1, 2016.
10.4 (5) (†)	Employment Agreement by and between the Company and Walter S. Woltosz, dated as of August 8, 2016.
10.5 (6)	Form of Indemnification Agreement.
10.6 (8)	2017 Equity Incentive Plan.
10.7 (7)	Stock Purchase Agreement by and among Simulation Plus, Inc., DILIsym Services, Inc., The Shareholders' Representative and The Shareholders of DILIsym Services, Inc., dated as of May 1, 2017.
10.8 (9)(†)	Employment Agreement by and between the Company and Walter S. Woltosz, dated as of September 1, 2017.
10.9 (9) (†)	Employment Agreement by and between the Company and John DiBella, dated as of September 1, 2017.
10.10 (9) (†)	Employment Agreement by and between the Company and Thaddeus H Grasela Jr., dated as of September 2, 2017.
10.11 (11) (†)	Employment Agreement by and between the Company and Shawn O'Connor, dated as of June 26, 2018.
31.1	Section 302 – Certification of the Principal Executive Officer*
31.2	Section 302 – Certification of the Principal Financial Officer*
32	Section 906 – Certification of the Chief Executive Office and Chief Financial Officer**
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

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^	Schedules and exhibits omitted pursuant to Item 601(b)(2) of Registration S-K. The registrant agrees to furnish supplementally a copy of any omitted schedule to the SEC upon request.
†	Those exhibits marked with a (†) refer to management contracts or compensatory plans or arrangements
*	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 an exhibit to the Company's Form 10-K for the fiscal year ended August 31, 2010.
(3)	Incorporated by reference to an exhibit to the Company's Form 10-Q filed April 9, 2014.
(4)	Incorporated by reference to an exhibit to the Company's Form 8-K/A filed November 18, 2014.
(5)	Incorporated by reference to an exhibit to the Company's Form 8-K filed August 11, 2016.
(6)	Incorporated by reference to an exhibit to the Company's Form 8-K filed August 10, 2016.
(7)	Incorporated by reference to an exhibit to the Company's Form 10-Q filed July 10, 2017.
(8)	Incorporated by reference to Appendix A to the Company's Schedule 14A filed December 29. 2016.
(9)	Incorporated by reference to an exhibit to the Company's Form 8-K filed September 6, 2017.
(10)	Incorporated by reference to an exhibit to the Company's Form 10-K for the fiscal year ended August 31, 2016.
(11)	Incorporated by reference to an exhibit to the Company's Form 10-Q filed July 10, 2018.

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 January 9, 2019.

Simulations Plus, Inc.

Date: January 9, 2019 By: /s/ *John R Kneisel*
John R. Kneisel

Chief Financial Officer