HALOZYME THERAPEUTICS INC
Form 10-Q
May 07, 2012
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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

# FORM 10-Q

(Mark One)

**[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended March 31, 2012**

**OR**

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

For the transition period from _____ to _____.

**Commission File Number 001-32335**

# HALOZYME THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **88-0488686** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **11388 Sorrento Valley Road, San Diego, CA** | **92121** |
| (Address of principal executive offices) | (Zip Code) |

**(858) 794-8889**

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ]

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

| Large accelerated filer ¨ | Accelerated filer x | Non-accelerated filer ¨ | Smaller reporting company ¨ |
|---|---|---|---|
| | | | (Do not check if a smaller reporting company) |

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

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, was 112,443,372 as of April 30, 2012.

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## PART I FINANCIAL INFORMATION

**Item 1. Financial Statements**

### HALOZYME THERAPEUTICS, INC.

### CONDENSED CONSOLIDATED BALANCE SHEETS

| | March 31, 2012 (Unaudited) | December 31, 2011 (Note) |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 116,608,304 | $ 52,825,527 |
| Accounts receivable, net | 5,550,830 | 2,262,465 |
| Inventories | 1,496,783 | 567,263 |
| Prepaid expenses and other assets | 8,910,059 | 8,332,242 |
| Total current assets | 132,565,976 | 63,987,497 |
| Property and equipment, net | 2,152,934 | 1,771,048 |
| Total Assets | $ 134,718,910 | $ 65,758,545 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,011,181 | $ 7,556,859 |
| Accrued expenses | 7,184,794 | 5,615,574 |
| Deferred revenue, current portion | 6,484,800 | 4,129,407 |
| Total current liabilities | 16,680,775 | 17,301,840 |
| Deferred revenue, net of current portion | 36,130,767 | 36,754,583 |
| Deferred rent, net of current portion | 846,957 | 802,006 |
| Commitments and contingencies (Note 10) | | |
| Stockholders equity: | | |
| Preferred stock $0.001 par value; 20,000,000 shares authorized; no shares issued and outstanding | - | - |
| Common stock $0.001 par value; 150,000,000 shares authorized; 112,411,014 and 103,989,272 shares issued and outstanding at March 31, 2012 and December 31, 2011, respectively | 112,411 | 103,990 |
| Additional paid-in capital | 341,088,827 | 255,817,772 |
| Accumulated deficit | (260,140,827) | (245,021,646) |
| Total stockholders equity | 81,060,411 | 10,900,116 |
| Total Liabilities and Stockholders Equity | $ 134,718,910 | $ 65,758,545 |

Note: The condensed consolidated balance sheet at December 31, 2011 has been derived from audited financial statements at that date. It does not include, however, all of the information and notes required by U.S. generally accepted accounting principles for complete financial statements.

See accompanying notes to condensed consolidated financial statements.

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**HALOZYME THERAPEUTICS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

**(UNAUDITED)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2012** | **2011** |
| Revenues: | | |
| Product sales, net | $ 187,411 | $ 165,449 |
| Revenues under collaborative agreements | 7,252,768 | 7,378,445 |
| Total revenues | 7,440,179 | 7,543,894 |
| Operating expenses: | | |
| Cost of product sales | 70,761 | 11,717 |
| Research and development | 15,891,109 | 13,785,797 |
| Selling, general and administrative | 6,618,707 | 3,405,966 |
| Total operating expenses | 22,580,577 | 17,203,480 |
| Operating loss | (15,140,398) | (9,659,586) |
| Interest and other income, net | 21,217 | 23,869 |
| Net loss | $ (15,119,181) | $ (9,635,717) |
| Basic and diluted net loss per share | $ (0.14) | $ (0.10) |
| Shares used in computing basic and diluted net loss per share | 107,589,514 | 100,927,402 |
| Comprehensive loss | $ (15,119,181) | $ (9,635,717) |

See accompanying notes to condensed consolidated financial statements.

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**HALOZYME THERAPEUTICS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(UNAUDITED)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2012** | **2011** |
| Operating activities: | | |
| Net loss | $ (15,119,181) | $ (9,635,717) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share-based compensation | 2,154,928 | 931,070 |
| Depreciation and amortization | 237,793 | 326,181 |
| Gain on disposals of equipment | (6,988) | (656) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | (3,288,365) | 596,943 |
| Inventories | (929,520) | (55,052) |
| Prepaid expenses and other assets | (577,817) | 337,903 |
| Accounts payable and accrued expenses | (3,609,171) | (2,771,781) |
| Deferred rent | 49,129 | (89,688) |
| Deferred revenue | 1,731,577 | (731,269) |
| Net cash used in operating activities | (19,357,615) | (11,092,066) |
| Investing activities: | | |
| Proceeds from disposals of property and equipment | 15,844 | - |
| Purchases of property and equipment | - | (203,023) |
| Net cash provided by (used in) investing activities | 15,844 | (203,023) |
| Financing activities: | | |
| Proceeds from issuance of common stock, net | 81,476,845 | - |
| Proceeds from exercise of stock options, net | 1,647,703 | 1,868,540 |
| Net cash provided by financing activities | 83,124,548 | 1,868,540 |
| Net increase (decrease) in cash and cash equivalents | 63,782,777 | (9,426,549) |
| Cash and cash equivalents at beginning of period | 52,825,527 | 83,255,848 |
| Cash and cash equivalents at end of period | $ 116,608,304 | $ 73,829,299 |
| Supplemental disclosure of non-cash investing and financing activities: | | |
| Accounts payable for purchases of property and equipment | $ 628,535 | $ 16,795 |

See accompanying notes to condensed consolidated financial statements.

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**HALOZYME THERAPEUTICS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**1. Organization and Business**

Halozyme Therapeutics, Inc. (referred to as we, us, Halozyme or the Company ) is a biopharmaceutical company dedicated to developing an commercializing innovative products that advance patient care. Our research targets the extracellular matrix, an area outside the cell that provides structural support in tissues and orchestrates many important biological activities, including cell migration, signaling and survival. Over many years, we have developed unique scientific expertise that allows us to pursue this target-rich environment for the development of future therapies.

Our research focuses primarily on human enzymes that alter the extracellular matrix. Our lead enzyme, recombinant human hyaluronidase ( rHuPH20 ), temporarily degrades hyaluronan, a matrix component in the skin, and facilitates the dispersion and absorption of drugs and fluids. We are also developing novel enzymes that may target other matrix structures for therapeutic benefit. Our Enhanze technology is the platform for the delivery of proprietary small and large molecules. We apply our research products in partnership with other companies as well as for our own proprietary pipeline in therapeutic areas with significant unmet medical need, such as diabetes, oncology and dermatology.

Our operations to date have involved: (i) organizing and staffing our operating subsidiary, Halozyme, Inc.; (ii) acquiring, developing and securing our technology; (iii) undertaking product development for our existing product and a limited number of product candidates; (iv) supporting the development of partnered product candidates and (v) selling *Hylenex*® recombinant (hyaluronidase human injection). We continue to increase our focus on our proprietary product pipeline and have expanded investments in our proprietary product candidates. We currently have multiple proprietary programs in various stages of research and development. In addition, we currently have collaborative partnerships with F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc. ( Roche ), Baxter Healthcare Corporation ( Baxter ), ViroPharma Incorporated ( ViroPharma ), and Intrexon Corporation ( Intrexon ), to apply Enhanze technology to these partners biological therapeutic compounds. Currently, we have received only limited revenue from the sales of *Hylenex* recombinant, in addition to other revenues from our partnerships.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The accompanying interim unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ( U.S. GAAP ) and with the rules and regulations of the U.S. Securities and Exchange Commission ( SEC ) related to a quarterly report on Form 10-Q. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for a complete set of financial statements. These interim unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2011, filed with the SEC on March 12, 2012. The unaudited financial information for the interim periods presented herein reflects all adjustments which, in the opinion of management, are necessary for a fair presentation of the financial condition and results of operations for the periods presented, with such adjustments consisting only of normal recurring adjustments. Operating results for interim periods are not necessarily indicative of the operating results for an entire fiscal year.

The condensed consolidated financial statements include the accounts of Halozyme Therapeutics, Inc. and our wholly owned subsidiary, Halozyme, Inc. All intercompany accounts and transactions have been eliminated.

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and

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accompanying notes. On an ongoing basis, we evaluate our estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management s estimates.

***Adoption of Recent Accounting Pronouncements***

Effective January 1, 2012, we adopted Financial Accounting Standards Board s ( FASB ) Accounting Standards Update ( ASU ) No. 2011-05, Comprehensive Income (Topic 220): *Presentation of Comprehensive Income* and ASU No. 2011-12, Comprehensive Income (Topic 220): *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU No. 2011-5*. In these updates, an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. ASU No. 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders equity. The amendments in ASU No. 2011-05 do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The amendments in these updates are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of ASU Nos. 2011-05 and 2011-12 did not have a material impact on our consolidated financial position or results of operations. We have presented comprehensive loss in our condensed consolidated statements of comprehensive loss.

Effective January 1, 2012, we prospectively adopted the FASB s ASU No. 2011-04, *Fair Value Measurement (Topic 820) Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS* . The amendments in ASU 2011-04 result in common fair value measurement and disclosure requirements in GAAP and International Financial Reporting Standards ( IFRS ). Consequently, the amendments change the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements. This pronouncement is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of ASU No. 2011-04 did not have a material effect on our consolidated financial position or results of operations.

***Inventories***

Inventories are stated at lower of cost or market. Cost, which includes amounts related to materials and costs incurred by our contract manufacturers, is determined on a first-in, first-out basis. Inventories are reviewed periodically for potential excess, dated or obsolete status. Management evaluates the carrying value of inventories on a regular basis, taking into account such factors as historical and anticipated future sales compared to quantities on hand, the price it expects to obtain for products in their respective markets compared with historical cost and the remaining shelf life of goods on hand.

Raw materials inventories consist of raw materials used in the manufacture of our bulk drug material for *Hylenex* recombinant product. Work-in-process inventories consist of in-process *Hylenex* recombinant. Finished goods inventories consist of finished *Hylenex* recombinant product.

We expense costs relating to the purchase and production of pre-approval inventories for which the sole use is pre-approval products as research and development expense in the period incurred until such time as we believe future commercialization is probable and future economic benefit is expected to be realized. For products that have been approved by regulatory bodies such as the U.S. Food and Drug Administration ( FDA ), inventories used in clinical trials are expensed at the time the inventories are packaged for the clinical trials. Prior to receiving approval from the FDA or comparable regulatory agencies in foreign countries, costs related to purchases of the active pharmaceutical ingredients ( API ) and the manufacturing of the product candidate are recorded as research and development expense. All direct manufacturing costs incurred after approval are capitalized as inventories.

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***Revenue Recognition***

We generate revenues from product sales and collaborative agreements. Payments received under collaborative agreements may include nonrefundable fees at the inception of the agreements, license fees, milestone payments for specific achievements designated in the collaborative agreements, reimbursements of research and development services and/or royalties on sales of products resulting from collaborative arrangements.

We recognize revenue in accordance with the authoritative guidance on revenue recognition. Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller s price to the buyer is fixed or determinable; and (4) collectibility is reasonably assured.

***Product Sales*** *Hylenex* recombinant was approved for marketing by the FDA in December 2005. From 2005 through January 7, 2011, Baxter had the worldwide market rights for *Hylenex* recombinant under the terms of the Hylenex Partnership. Baxter commercially launched *Hylenex* recombinant in October 2009. However, *Hylenex* recombinant was voluntarily recalled in May 2010 because a portion of the product manufactured by Baxter was not in compliance with the requirements of the underlying partnership. Effective January 7, 2011, we and Baxter mutually agreed to terminate the Hylenex Partnership. During the second quarter of 2011, we submitted the data that the FDA had requested to support the reintroduction of *Hylenex* recombinant to the market. The FDA approved the submitted data and granted the reintroduction of *Hylenex* recombinant.

In December 2011, we reintroduced *Hylenex* recombinant to the market, shipped initial stocking orders to our wholesaler customers and began promoting *Hylenex* recombinant through our sales force. We sell *Hylenex* recombinant in the United States to wholesale pharmaceutical distributors, who sell the product to hospitals and other end-user customers. The wholesale distributors take title to the product, bear the risk of loss of ownership and have economic substance to the inventory. Further, we have no significant obligations for future performance to generate pull-through sales; however, we do allow the wholesale distributors to return product that is damaged or received in error. In addition, we allow for product to be returned beginning six months prior to and ending twelve months following product expiration. Given our limited history of selling *Hylenex* recombinant and the lengthy return period, we currently cannot reliably estimate expected returns and chargebacks of *Hylenex* recombinant at the time the product is received by the wholesale distributors. Therefore, we do not recognize revenue upon delivery of *Hylenex* recombinant to the wholesale distributor until the point at which we can reliably estimate expected product returns and chargebacks from the wholesale distributors. Shipments of *Hylenex* recombinant are recorded as deferred revenue until evidence exists to confirm that pull-through sales to the hospitals or other end-user customers have occurred. We recognize revenue when the product is sold through from the distributors to the distributors customers. In addition, the costs of manufacturing *Hylenex* recombinant associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time as the related deferred revenue is recognized. We estimate sell-through revenue and certain gross to net sales adjustments based on analysis of third-party information including information obtained from certain distributors with respect to their inventory levels and sell-through to the distributors customers. At the time we can reliably estimate product returns and chargebacks from the wholesale distributors, we will record a one-time increase in net product sales revenue related to the recognition of product sales revenue previously deferred.

We recognize product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with wholesale distributors and hospitals and the levels of inventory within the distribution channels that may result in future discounts taken. We must make significant judgments in determining these allowances. If actual results differ from our estimates, we will be required to make an adjustment to these allowances in the future, which could have an effect on product sales revenue in the period of adjustment. Our product sales allowances include:

*Distribution Fees*. The distribution fees, based on contractually determined rates, arise from contractual agreements we have with certain wholesale distributors for distribution services they provide with respect to *Hylenex* recombinant. At the time the sale is made to the respective wholesale distributors, we record an allowance for distribution fees by reducing our accounts receivable and deferred revenue associated with such product sales.

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*Prompt Payment Discounts*. We offer cash discounts to certain wholesale distributors as an incentive to meet certain payment terms. We expect our customers will take advantage of this discount; therefore, at the time the sale is made to the respective wholesale distributors, we accrue the entire prompt payment discount, based on the gross amount of each invoice, by reducing our accounts receivable and deferred revenue associated with such product sales.

*Chargebacks*. We provide discounts to certain hospitals. These hospitals purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to us the difference between the current retail price and the price the hospitals paid for the product. Given our lack of historical sales data, we recognize chargebacks in the same period the related product sales revenue is recognized and reduce our accounts receivable accordingly.

*Product Returns*. The product returns reserve is based on management s best estimate of the product sales recognized as revenue during the period that are anticipated to be returned. The product returns reserve is recorded as a reduction of product sales revenue in the same period the related product sales revenue is recognized and is included in accrued expenses.

***Revenues under Collaborative Agreements*** We have entered into license and collaboration agreements under which the collaborative partners obtained worldwide exclusive rights for the use of our proprietary rHuPH20 enzyme in the development and commercialization of the partners biologic compounds. The collaborative agreements contain multiple elements, including nonrefundable payments at the inception of the arrangements, license fees, exclusivity fees, payments based on achievement of specified milestones designated in the collaborative agreements, reimbursements of research and development services, payments for supply of rHuPH20 API for the partner and/or royalties on sales of products resulting from collaborative agreements. We analyze each element of the collaborative agreements and consider a variety of factors in determining the appropriate method of revenue recognition of each element.

Prior to the adoption of ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, on January 1, 2011, in order for a delivered item to be accounted for separately from other deliverables in a multiple-element arrangement, the following three criteria had to be met: (i) the delivered item had standalone value to the customer, (ii) there was objective and reliable evidence of fair value of the undelivered items, and (iii) if the arrangement included a general right of return relative to the delivered item, delivery or performance of the undelivered items was considered probable and substantially in the control of the vendor. For the collaborative agreements entered into prior to January 1, 2011, there was no objective and reliable evidence of fair value of the undelivered items. Thus, the delivered licenses did not meet all of the required criteria to be accounted for separately from undelivered items. Therefore, we recognized revenue on nonrefundable upfront payments and license fees from these collaborative agreements over the period of significant involvement under the related agreements.

For new collaborative agreements or material modifications of existing collaborative agreements entered into after December 31, 2010, we follow the provisions of ASU No. 2009-13. In order to account for the multiple-element arrangements, we identify the deliverables included within the agreement and evaluate which deliverables represent units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. The deliverables under our collaborative agreements include (i) the license to rHuPH20 technology, (ii) at the collaborator s request, research and development services which are reimbursed at contractually determined rates, and (iii) at the collaborator s request, supply of rHuPH20 API which is reimbursed at our cost plus a margin. A delivered item is considered a separate unit of accounting when the delivered item has value to the collaborator on a standalone basis based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of research expertise in this field in the general marketplace.

Arrangement consideration is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. The relative selling price for each deliverable is determined using vendor specific objective evidence ( VSOE ) of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, we use our best estimate of the selling price for the deliverable. The amount of allocable arrangemeE="width: 2%; padding-bottom: 1pt"> $809,864 $1,061,575 $1,495,019 $1,648,561 Denominator: Weighted-average number of common shares outstanding during the period 16,107,327 16,004,397 16,078,173 15,965,890 Dilutive effect of stock options 249,217 331,956 241,729 339,345 Common stock and common stock equivalents used for diluted earnings per share 16,356,544 16,336,353 16,319,902 16,305,235

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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 FASB ASC 718-10, amortized on a straight-line basis over the options' vesting period. Stock-based compensation was $71,087 and $70,253 for the six months ended February 28, 2014 and 2013, respectively, and was $55,727 and $32,154 for the three months ended February 28, 2014 and 2013, respectively. This expense is included in the condensed statements of operations as Selling, General and Administration (SG&A), and Research and Development expense.

Recently Issued Accounting Pronouncements

In July 2012, the FASB issued ASU 2012-02, "*Testing Indefinite-Lived Intangible Assets for Impairment",* which amended the guidance in ASU 2011-08 to simplify the testing of indefinite-lived intangible assets other than goodwill for impairment. ASU 2012-02 becomes effective for annual and interim impairment tests performed for fiscal years beginning on or after September 15, 2012 and earlier adoption is permitted. We adopted this standard in the first quarter of fiscal year 2013. We believe adoption did not have a material effect on our financial statements.

In July 2013, the FASB issued ASU 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists*, which eliminates diversity in practice for the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss or a tax credit carryforward is available to reduce the taxable income or tax payable that would result from disallowance of a tax position. ASU 2013-11 affects only the presentation of such amounts in an entity's balance sheet and is effective for fiscal years beginning after December 15, 2013 and interim periods within those years. Early adoption is permitted. We are evaluating the impact, if any, of the adoption of ASU 2013-11 on our balance sheet.

Note 3: Property and Equipment

Property and equipment as of February 28, 2014 consisted of the following:

| | |
|---|---|
| Equipment | $124,042 |
| Computer equipment | 142,907 |
| Furniture and fixtures | 51,466 |

| | |
|---|---|
| Leasehold improvements | 23,645 |
| Sub total | 342,059 |
| Less: Accumulated depreciation and amortization | (229,592) |
| Net Book Value | $112,467 |

Note 4: COMMITMENTS AND CONTINGENCIES

Employment Agreement

On July 22, 2012, the Company entered into an employment agreement with its President/Chief Executive Officer that expired in August 2013. The employment agreement provided for an annual base salary of $300,000 per year, and a performance bonus in an amount not to exceed 10% of Employee's salary, or $30,000 per year, at the end of each fiscal year. The specific amount of the bonus to be awarded will be determined by the Compensation Committee of the Board of Directors, based on the financial performance and achievements of the Company for the previous fiscal year. The agreement also provides Employee stock options, exercisable for five years, to purchase fifty (50) shares of Common Stock for each one thousand dollars ($1,000) of net income before taxes at the end of each fiscal year up to a maximum of 120,000 options over the term of the agreement. The agreement allows the Company to terminate the agreement upon 30 days written notice, if termination is without cause, the Company's only obligation would be to pay its President the greater of a) 12 month's salary or b) the remainder of the term of the employment agreement from the date of notice of termination.

For fiscal year 2013, the Compensation Committee awarded a $30,000 performance bonus to Walter Woltosz, our President/Chief Executive Officer, which was paid in September 2013.

On August 22, 2013, effective as of September 1, 2013, the CEO's employment agreement was renewed for another year by the Compensation Committee and provides for an annual bonus of up to five percent (5%) of the Company's net income before taxes of the previous fiscal year not to exceed $60,000. In addition the agreement calls for the granting of ten (10) options to purchase shares of the Company's common stock for each $1,000 of net income before taxes that the Company earns at the end of each fiscal year (up to a maximum of twenty thousand (20,000) options over the term of the agreement) at an exercise price equal to ten percent (10%) over the market value per share as of the date of grant (the number of shares to be adjusted accordingly for any stock splits or reverse splits after the date of the agreement). A copy of the agreement is attached to the Company's 2013 Form 10-K filed with the SEC on November 18, 2013 as Exhibit 10.9.

Litigation

We are not a party to any litigation at this time and we are not aware of any pending litigation of any kind.

Note 5: SHAREHOLDERS' EQUITY

Dividend

The Board of Directors declared cash dividends during fiscal year 2013. The details of dividends paid are in the following table:

| Record Date | Distribution Date | Number of Shares Outstanding on Record Date | Dividend per Share | Total Amount |
|---|---|---|---|---|
| 11/8/2012 | 11/13/2012 | 15,927,806 | $ 0.05 | $796,390 |
| 12/24/2012 | 12/28/2012 | 16,021,309 | $ 0.14 | $2,242,983 |
| 5/7/2013 | 5/10/2013 | 16,030,433 | $ 0.03 | $480,913 |
| 8/12/2013 | 8/15/2013 | 16,030,894 | $ 0.03 | $480,926 |
| Total | | | | $4,001,212 |

The Board of Directors has also declared cash dividends during fiscal year 2014. The details of dividends paid are in the following table:

| Record Date | Distribution Date | Number of Shares Outstanding on Record Date | Dividend per Share | Total Amount |
|---|---|---|---|---|
| 11/08/2013 | 11/15/2013 | 16,073,894 | $ 0.04 | $642,956 |
| 2/17/2014 | 2/24/2014 | 16,149,460 | $ 0.05 | $807,473 |
| Total | | | | $1,450,429 |

Stock Option Plan

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

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

Qualified Incentive Stock Options (Qualified ISO)

As of February 28, 2014, employees hold Qualified ISO to purchase 479,000 shares of common stock at exercise prices ranging from $1.00 to $5.61 which were granted prior to February 28, 2014.

| Transactions in FY14 | Number of Options | Weighted-Average Exercise Price Per Share | Weighted-Average Remaining Contractual Life |
|---|---|---|---|
| Outstanding, August 31, 2013 | 532,000 | $ 1.82 | 3.95 |
| Granted | 100,000 | $ 5.61 | |
| Exercised | (147,000) | $ 1.29 | |
| Cancelled/Forfeited | (6,000) | $ 1.00 | |
| Outstanding, February 28, 2014 | 479,000 | $ 2.78 | 3.88 |
| Exercisable, February 28, 2014 | 289,600 | $ 1.85 | 3.43 |

The fair value of the options, including both ISO and NQSO options, granted during the six months ended February 28, 2014 is estimated at $130,781. The fair value of these options was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions for FQE February 28, 2014: dividend yield of 3.14%, pre-vest forfeiture rate of 6.25%, expected volatility of 38.95%, risk-free interest rate of 1.36%, and expected life of 5.0 years.

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Non-Qualified Stock Options (Non-Qualified ISO)

As of February 28, 2014, the outside members of the Board of Directors hold options to purchase 45,600 shares of common stock at exercise prices ranging from $1.67 to $6.68, which were granted prior to February 28, 2014.

| Transactions in FY14 | Number of Options | Weighted-Average Exercise Price Per Share | Weighted-Average Remaining Contractual Life |
|---|---|---|---|
| Outstanding, August 31, 2013 | 48,600 | $ 3.79 | 7.85 |
| Exercised | (3,000) | $ 1.80 | |
| Outstanding, February 28, 2014 | 45,600 | $ 3.92 | 7.54 |
| Exercisable, February 28, 2014 | 25,200 | $ 3.45 | 6.37 |

The weighted-average remaining contractual life of options outstanding issued under the Plan, both Qualified ISO and Non-Qualified SO, was 4.19 years at February 28, 2014. The exercise prices for the options outstanding at February 28, 2014 ranged from $1.00 to $6.68, and the information relating to these options is as follows:

| Exercise Price | | Awards Outstanding | | | Awards Exercisable | | |
|---|---|---|---|---|---|---|---|
| Low | High | Quantity | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price | Quantity | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price |
| $1.00 | $1.50 | 215,100 | 3.81 | $ 1.05 | 187,700 | 3.62 | $1.06 |
| $1.51 | $3.00 | 31,600 | 6.12 | $ 2.35 | 11,600 | 3.08 | $2.11 |
| $3.01 | $4.50 | 141,900 | 3.63 | $ 3.28 | 103,500 | 3.49 | $3.22 |
| $4.51 | $6.68 | 136,000 | 4.95 | $ 5.49 | 12,000 | 3.52 | $5.59 |
| | | 524,600 | 4.19 | $ 2.88 | 314,800 | 3.67 | $1.98 |

NOTE 6: RELATED PARTY TRANSACTIONS

As of February 28, 2014, included in bonus expenses to officers was $90,000, of which $30,000 was accrued bonus representing an estimated quarterly amount of bonus payable to the Corporate Secretary, Virginia Woltosz, as part of the terms of the sale of Words+ to Simulations Plus in 1996, and $30,000 accrued bonus representing an estimated quarterly amount of bonus payable to our President/Chief Executive Officer, Walter Woltosz as part of his 2014

employment agreement The other $30,000, paid in September 2013, was FY2013 performance bonus to Walter Woltosz, our President/Chief Executive Officer, which was approved by the compensation committee in September 2013.

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NOTE 7: CONCENTRATIONS AND UNCERTAINTIES

Revenue concentration shows that International sales accounted for 61% and 53% of net sales for the six months ended February 28, 2014 and 2013, respectively. One customer (a dealer account in Japan representing various customers) accounted for 10% of sales for the six months ended February 28, 2014 compared to two customers who accounted for 11% (a dealer account in Japan representing various customers) and 10% of net sales during the six months ended February 28, 2013.

Accounts receivable concentration shows that two customers comprised 13% (a dealer account in Japan representing various customers) and 11% of accounts receivable at February 28, 2014 compared to three customers comprising 12%, 10% (a dealer account in Japan representing various customers), and 10% of accounts receivable at February 28, 2013.

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. During the current economic downturn, we have seen consolidations in the pharmaceutical industry, especially in this first fiscal quarter of 2013. Although we have not seen any significant reduction in total revenues to date, our growth rate has been affected. Continued consolidation and downsizing in the pharmaceutical industry could have an impact on our revenues and earnings going forward.

NOTE 8: Geographic Reporting

We allocate revenues to geographic areas based on the locations of our customers. Geographical revenues for the six months ended February 28, 2014 and 2013 were as follows (in thousands):

| Six month ended | North America | Europe | Asia | South America | Total |
|---|---|---|---|---|---|
| February 28, 2014 | $ 2,228 | $1,968 | $1,515 | $ 11 | $5,722 |
| February 28, 2013 | $ 2,605 | $1,775 | $1,028 | $ – | $5,408 |

Note 9: 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 $61,756 and $50,545 for the six months ended February 28, 2014 and 2013, respectively, and $35,629 and $29,731 for the three months ended February 28, 2014 and 2013, respectively.

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

**Forward-Looking Statements**

This document and the documents incorporated in this document by reference contain forward-looking statements that are subject to risks and uncertainties. All statements other than statements of historical fact contained in this document and the materials accompanying this document are forward-looking statements.

The forward-looking statements are based on the beliefs of our management, as well as assumptions made by and information currently available to our management. Frequently, but not always, forward-looking statements are identified by the use of the future tense and by words such as “believes,” expects,” “anticipates,” “intends,” “will,” “may,” “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**

Simulations Plus, Inc., incorporated in 1996, develops and produces software for use in pharmaceutical research and for education, as well as provides contract research services to the pharmaceutical industry.

We currently offer five software products for pharmaceutical research: ADMET Predictor™, MedChem Designer™, MedChem Studio™, DDDPlus™, and GastroPlus™. We call the combination of ADMET Predictor, MedChem Studio, and MedChem Designer our ADMET Design Suite™.

*ADMET Predictor*™

ADMET (Absorption, Distribution, Metabolism, Excretion, and Toxicity) Predictor is a computer program that takes molecular structures as inputs and predicts over 140 different properties for them at the rate of over 100,000 compounds per hour on a fast laptop computer. This capability allows chemists to get estimates for a large number of important properties without the need to synthesize and test the molecules. ADMET Predictor has been consistently top-ranked for predictive accuracy in peer-reviewed, independent comparison studies, while generating its results at a very high throughput rate. Although the state-of-the-art of this type of software does not enable finding the best molecule in a series, it does allow identifying molecules that are highly likely to fail as potential drug candidates (the worst molecules, which is usually the majority of a chemical library) before synthesizing and testing them. Thus, millions of "virtual" compounds can be created and screened in a day, compared to potentially months or years of work to actually synthesize and test a much smaller number of actual compounds.

The ADMET Modeler™ subprogram that is integrated into ADMET Predictor enables scientists to use their own experimental data to quickly create high-quality, proprietary predictive models using the same powerful modeling methods we use to build our top-ranked property predictions. Pharmaceutical companies expend substantial time and money conducting a wide variety of experiments on new molecules each year, resulting in large databases of experimental data. Using this proprietary data to build predictive models can provide a second return on their investment; however, model building has traditionally been a difficult and tedious activity performed by specialists. The automation in ADMET Modeler makes it easy for a scientist to create very powerful models with a minimum of training.

We are now examining a very different application of this modeling engine – building predictive models for missile aerodynamic force coefficients as a function of missile geometry, Mach number, and angle of attack. This problem was identified by the Aerospace Engineering department at Auburn University, and working with them, we have done some preliminary testing of the modeling engine in ADMET Modeler for this type of problem. Results have been very encouraging, and we believe there are government agencies and industrial aerospace companies that will find such a capability to be highly useful. We have developed a prototype AEROModeler™ program to test this concept and to use as a demonstrator for proposal efforts to potential funding agencies. Our proposed joint scientific poster on this subject with Auburn University's Aerospace Engineering Department was selected for presentation at the NSMMS/CRASTE (National Space and Missile Material Symposium/Commercial and Government Responsive Access to Space Technology Exchange) conference in Huntsville, Alabama in June 2014.

We have also begun a preliminary investigation of applying this powerful modeling engine to the analysis of MRI (magnetic resonance imaging) data in cooperation with the MRI facility at Auburn University. This state-of-the-art facility has two MRIs – one a 3-Tesla machine and one a very powerful 7-Tesla machine, both built in the last few years. We are examining data from a series of subjects in four groups: healthy, PDD (Pervasive Developmental Disorder), ADHD (Attention Deficit Hyperactivity Disorder), and Asperger's Syndrome to determine whether we can discriminate between the groups from the MRI imaging data. This is a problem that has defied solution so far, so it is a speculative effort involving minimal resources to determine whether we can show proof-of-concept. Our ability to

process the data is not in question; rather, we need to determine whether the data contains sufficient information to discriminate between the different groups. The amount of data is massive (“big data”), requiring us to modify our code to handle much larger data arrays than our previous applications have required. Our goal is to show the potential of our modeling technology to provide useful classification of a subject into one of the four groups based only on MRI imaging so that we could go to various agencies (such as the National Institutes of Health) to obtain funding to develop a commercial product.

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We released Version 6.5 of ADMET Predictor during last fiscal year. This version extended our metabolism predictions by training on a much larger experimental data set, and for the first time, provided specific metabolism rates for individual atoms within a molecule, rather than only for the molecule as a whole. These improvements are also available via MedChem Designer and MedChem Studio for customers who license ADMET Predictor. Version 6.5 also adds confidence levels to most of our toxicity models so that users have an idea of the reliability of each individual prediction.

After the end of this reporting period, we released version 7.0. This new version incorporates a new model for predicting ionization constants (pKa's), developed in a collaboration with Bayer AG that enabled us to more than double the size of our data set from about 16,000 pKa values to more than 35,000, and to expand the chemical space it covers to include a larger number of molecules more like those of interest to the pharmaceutical industry today. We believe the resulting improvement in pKa prediction puts our already best-in-class model well in front of any competitor**.** Predicting ionization is critical to predicting most other properties, so all of our models (approximately 144) were retrained based on this new capability for version 7.0.

*MedChem Designer*™

MedChem Designer was launched in 2011. It was initially a molecule drawing program, or "sketcher", but now has capabilities exceeding those of other molecule drawing programs because of its integration with both MedChem Studio and ADMET Predictor. We provide MedChem Designer for free because we believe that in the long run it will help to increase demand for ADMET Predictor and MedChem Studio, and because most other existing molecule drawing programs are also free. Our free version includes a small set of ADMET Predictor property predictions, allowing the chemist to modify molecular structures and then see a few key properties very quickly. The chemist also sees that with a paid ADMET Predictor license, the entire 140+ predictions would be available.

We released MedChem Designer 2.5 during FY2013. This version provided specific predicted atom locations for metabolism by each of the enzymes predicted to act upon a molecule.

When coupled with a license for ADMET Predictor, MedChem Designer becomes a *de novo* design tool for medicinal chemists. With it, they can draw one or more molecular structures, then click on the ADMET Predictor icon and have over 140 properties for each structure calculated in seconds, including our proprietary ADMET Risk™ index. Scientists 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 their ADMET Risk scores. This is important because a metabolite of a molecule can be harmful even though the parent molecule is not.

ADMET Risk provides a single number that tells the chemist how many default threshold values for 24 predicted properties were crossed (or violated) by each structure. The rules can be modified and new rules added by the user to include any desired rule set based on any combination of calculated descriptors, predicted properties, and user inputs. Thus, in a single number, the chemist can instantly compare the effects of different structural changes in many dimensions. As chemists attempt to modify structures to improve one property, they often cause others to become unacceptable. Without ADMET Risk, the chemist would have to individually examine many key properties for each new molecule (and its metabolites) to check whether any of them became unacceptable as a result of changing the structure.

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We are now finalizing version 3.0 of MedChem Designer, which will add the ability to capture the image of a molecular structure from a variety of publication files with a new snapshot tool, and the program will automatically convert the graphic image into any of several computer-based chemical structure files. Converting from lines and letters on the screen to an exact chemical representation of the molecule (Optical Structure Recognition, or OSR) is a complex task. Although a few OSR programs are in existence, we are not aware of any that can accurately convert as many varieties of images to chemical representation as the OSR tool within the development version of MedChem Designer. Such a capability allows chemists to quickly capture molecular structures from the scientific literature to use in our simulation and modeling software.

*MedChem Studio*™

Over the past several years, MedChem Studio updates have resulted in a very powerful tool for medicinal and computational chemists for both data mining and for designing new drug-like molecules. We released version 3.5 of MedChem Designer during FY2013. The new features included such important items as:

A new licensing module from Flexera called FlexNet™

Improvements to graphics in structure depictions and the Miner 3D module

Faster performance on large data sets

A 64-bit version to deal with much larger data sets

User-defined equations to calculate new attributes by combining others

Enhanced Miner3D graphics with expanded assortment of chart types

While MedChem Designer can be used to refine a small number of molecules, MedChem Studio can be used to create and screen (with ADMET Predictor) a very large number 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. Coupled with ADMET Predictor and MedChem Designer, we believe the programs provide an unmatched capability for chemists to search through large libraries of compounds that have undergone high-throughput screening experiments to find the most promising classes (groups of molecules with a large part of their structures the same) and molecules that are active against a particular target. In addition, MedChem Studio can take an interesting (but not acceptable) molecule and, using a variety of design algorithms, very 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 both active against the target as well as acceptable in a variety of ADMET properties.

MedChem Studio version 4.0 is now in final development and is expected to be released shortly after the ADMET Predictor 7.0 release to allow for proper synchronization between the two programs. Current development has focused primarily on the OSR tool mentioned above under the MedChem Designer discussion.

*NCE Projects*

During late 2012, based on our strong belief in the exceptional capabilities of our ADMET Design Suite (MedChem Studio/MedChem Designer/ADMET Predictor), we initiated a new molecule (NCE, or New Chemical Entity) design project. After considering various targets, we selected the malaria parasite Plasmodium falciparum, both because of the unmet need for a very low-cost cure, and because we believed that external funding opportunities might exist if we were successful in generating high-quality lead compounds using our software. Our goal was to demonstrate how well the ADMET Design Suite worked to generate new lead molecules in a fraction of the time and cost normally required in the pharmaceutical industry. We completed the design process in September 2012 and we announced that we had requested quotations from chemical synthesis companies for the cost and time to make a small set of molecules. Five molecules of our own design and two precursors (almost the final designed structures, but a step away in synthesis) were synthesized and tested for inhibition of the parasite at the University of California at Riverside. We were hoping that at least one would show inhibition of the growth cycle of the parasite.

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

During the previous reporting period, we announced that we had completed the design of a number of new molecules for a different target – the cyclo-oxygenase-2 (COX-2) enzyme that is the target for Celebrex®. Celebrex is the only COX-2 inhibitor remaining on the market, after the withdrawal of other approved drugs (such as Vioxx®) due to cardiac toxicity. It appears from the scientific research that was conducted after the withdrawal of other COX-2 inhibitors from the market that it is important to inhibit both COX-2 and COX-1 at a certain ratio in order to provide the benefits of COX-2 inhibition without the cardiotoxicity risk that has been associated with inhibiting COX-2 alone. We designed our new molecules based on activity models for both COX-2 and COX-1 built from public data, with the goal of providing an acceptable ratio of COX-2 to COX-1 inhibition. This is more challenging than designing for a single target, as we did for the earlier malaria NCE project. Results reported after the end of this reporting period showed that we were once again very successful, with all four molecules that were synthesized inhibiting both the COX-2 and COX-1 enzymes, and one of them providing the desired characteristic of higher affinity for COX-2 than COX-1. This is a remarkable achievement, and once again demonstrates that our ADMET Design Suite can save considerable time and money in developing new lead compounds for particular targets.

*DDDPlus*

DDDPlus simulates *in vitro* laboratory experiments used to measure the rate of dissolution of the drug and, if desired, the additives (excipients) contained in tablets and capsules under a variety of experimental conditions. This software program is used by formulation scientists in industry and the U.S. Food and Drug Administration (FDA) to (1) understand the physical mechanisms affecting the dissolution rate for various formulations, (2) reduce the number of cut-and-try attempts to design new drug formulations, and (3) to design in vitro dissolution experiments to better mimic in vivo conditions.

*GastroPlus*

Our flagship product and largest source of revenues is GastroPlus. GastroPlus simulates the absorption, pharmacokinetics, and pharmacodynamics of drugs administered to humans and animals, and is currently in widespread use at pharmaceutical companies, the FDA, the U.S. National Institutes of Health (NIH), and other government agencies in the U.S. and other countries. Because of 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 is a collaboration among 27 industry, academic, and government organizations working in the area of oral absorption of pharmaceutical products. Because we are outside of Europe, our participation in this project is at our own expense, while other members are compensated for their work; however, we are a full member with access to all of the data and discussions of all other members. We believe participation in this initiative enables us to benefit from and to contribute to advancing the prediction of human oral absorption from preclinical data, and ensures that we are in front of the audience of member pharmaceutical companies and regulatory agencies.

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

A new model for precipitation based on classical nucleation theory

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

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

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

An interim release (8.6) is planned for the very near future to enable certain customers to take advantage of a new physiological model for minipig, which has become a more frequently used animal species in preclinical development, and to add the ability to simulate populations within the Drug-drug interaction Module.

The next major release, version 9.0, is now well along in development. This version will add the ability to simulate dermal (through the skin) drug absorption from patches, creams, and ointments. This capability has been in development since May of 2012 through a funded collaboration with a top-5 pharmaceutical company, and is already in use at the customer's sites at this time. A number of other improvements will be included in version 9.0 that will be announced with the release of the product.

*MembranePlus*™

MembranePlus is a new product that has been under development for a number of years, but was put on hold for several years due to other priorities. It was revived in the past year and is now nearing commercial release. Like DDDPlus, MembranePlus simulates laboratory experiments, but in this case, the experiments are for measuring permeability of drug-like molecules through various membranes, including several different cell cultures (Caco-2, MDCK) as well as artificially formulated membranes (PAMPA). The value of such a simulation results from the fact that when the permeabilities of the same molecules are measured in different laboratories, results are often strikingly 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 the scientist to better interpret how results from specific experimental protocols can be used to predict permeability in human and animals, which is the ultimate goal. MembranePlus is unique and our customers have expressed significant interest in the new capability.

Priorities for developing material for our imminent training workshops required us to delay the development work on MembranePlus. We now plan to release version 1.0 of MembranePlus in the third fiscal quarter.

*Contract Research and Consulting Services*

Our expertise in oral absorption and pharmacokinetics is evidenced by the fact that our staff members have been speakers or presenters at over 80 scientific meetings worldwide in the past four years. We frequently conduct contracted studies for large customers (including the largest five pharmaceutical companies) who have particularly difficult problems and who recognize our expertise in solving them, as well as for smaller customers who prefer to have studies run by our scientists rather than to license our software and train someone to use it. The demand for our consulting services has been steadily increasing, and we have expanded our Simulations Studies team to meet the increased workload. Long-term collaborations and shorter-term consulting contracts serve both to expand and showcase our technologies, and to build and strengthen customer relationships.

During the second quarter of fiscal year 2014 we continued to work on our 5-year Research Collaboration Agreement (RCA) with the Center for Food Safety and Applied Nutrition (CFSAN) of the FDA. FDA scientists and our scientists are using ADMET Predictor/Modeler to build predictive models for likely toxicities of food additives and contaminants. During the first part of this collaboration, we analyzed FDA databases and worked with FDA scientists to ensure that the FDA data to be used for building new predictive models is as accurate as we can reasonably make it. Both FDA scientists and our scientists are building a series of models to classify new compounds as toxic or nontoxic from FDA datasets. Included early on in this effort was a special modification to ADMET Predictor to allow the user to set a minimum value for specificity or sensitivity when building a model, and this is now a standard part of the program available to all users. Sensitivity refers to how well a model identifies toxic (or any other property) compounds. A model that determined all compounds are toxic would have 100% sensitivity, because all toxic compounds would be labeled as such; however, all nontoxic compounds would also be labeled toxic. Specificity refers to how well a model distinguishes between toxic and nontoxic compounds. Increasing one usually results in decreasing the other. Depending on the purpose of the model, some scientists will prefer to train models that emphasize one statistic over the other.

After the end of this reporting period, we announced another five-year RCA, this time with the Office of Generic Drugs (OGD) within the FDA. This RCA is directed toward the FDA’s evaluation of mechanistic IVIVCs (in vitro-in vivo correlations), an approach to determine whether mechanistic absorption modeling (MAM) correlates laboratory (*in vitro*) dissolution experiments with the *in vivo* behavior of a dosage form better than traditional empirical methods. We have proposed this method for about 15 years and believe in it, so we are pleased to see the FDA giving it serious consideration with this RCA.

**STRATEGY**

Our business strategy is to do the things we need to do to promote growth both organically (by expanding our current products and services through in-house efforts) and by acquisition. We believe in the “Built to Last” approach - that the fundamental science and technologies that underlie our business units are the keys both to improving our existing

products and to expanding the product line with new products that meet our various customers' needs.

With our significant cash reserves, seeking suitable acquisitions is a priority. Because we have been unable to identify suitable acquisitions and our cash continues to accumulate, the board of directors declared a $0.05 per share per quarter cash dividend that began in February 2012 and was paid in May, August, and November 2012. The board declared an accelerated cash dividend consisting of the February, 2013 dividend of $0.05 per share per quarter plus $0.03 per share from each of the expected May, August, and November 2013 dividends of $0.05 per share per quarter for a total of $0.14 per share, which was distributed on December 28, 2012, in order to provide our shareholders with the income tax benefits from lower capital gains rates in 2012 over 2013. We declared a $.04 per share dividend in November 2013 and a $.05 per share dividend in February 2014. We anticipate the dividend to be $0.05 per share per quarter, however there can be no assurances that such dividends will be distributed, or if so, whether the amounts will be more, less, or the same as expected. The Board of Directors must approve each dividend distribution and may decide to increase, decrease, or eliminate dividend distributions at any time.

**Results of Operations**

***Comparison of Three Months Ended February 28, 2014 and 2013.***

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 | | | |
|---|---|---|---|---|
| | 02/28/14 | | 02/28/13 | |
| Net sales | $3,081 | 100.0% | $3,118 | 100.0% |
| Cost of sales | 492 | 16.0 | 499 | 16.0 |
| Gross profit | 2,589 | 84.0 | 2,619 | 84.0 |
| Selling, general and administrative | 1,104 | 35.8 | 855 | 27.4 |
| Research and development | 354 | 11.5 | 248 | 7.9 |
| Total operating expenses | 1,458 | 47.3 | 1,103 | 35.3 |
| Income from operations | 1,144 | 36.7 | 1,517 | 48.7 |
| Other income | 12 | 0.4 | 55 | 1.8 |
| Income from operations before taxes | 1,144 | 37.1 | 1,572 | 50.4 |
| (Provision for) income taxes | (334 ) | (10.8) | (511 ) | (16.0) |
| Net income | $810 | 26.3% | $1,062 | 34.0% |

*Net Sales*

Net sales decreased $37,000, or 1.2%, to $3,081,000 in the second quarter of Fiscal Year 2014 (“2QFY14”) from $3,118,000 in the second fiscal quarter of Fiscal Year 2013 (“2QFY13)”. Although software sales to new customers were very strong during the quarter, these increases were not able to compensate for a major customer deciding to move a global renewal order that had been received in the second fiscal quarter last year to the third fiscal quarter this year in order to synchronize with their internal budget timelines. Analytical study revenues decreased by $112,000 during the quarter as a consulting study contract from another client was delayed by their legal review process. The total effect on revenues of the customer budget timing and the delay in the study contract totaled approximately $350,000.

*Cost of Sales*

Cost of sales decreased by $7,000, or 1.3%, to $492,000 in 2QFY14 from $499,000 in 2QFY13. As a percentage of revenue, remained constant at 16% in 2QFY14 and 2QFY13. A significant portion of cost of sales for pharmaceutical software products is the systematic amortization of capitalized software development costs. Amortization cost increased approximately $15,000, or 9%, in 2QFY14 compared with 2QFY13. Royalty expense, another significant

portion of cost of sales, decreased approximately $30,000, or 13%, in 2QFY14 compared with 2QFY13. We pay a royalty on the core GastroPlus software licenses but not on its optional modules. We also pay royalties to Accelrys on a portion of the ADMET Predictor Metabolism Module. Workshop/Training costs increased by $23,000 as we did more workshop programs and more onsite training in 2QFY14 compare to 2QFY13.

*Gross Profit*

Gross profit decreased $7,000, or 0.7%, to $2,589,000 in 2QFY14 from $2,619,000 in 2QFY13. We attribute this decrease to the decreased revenues outweighing the decrease in cost of sales.

*Selling, General and Administrative Expenses*

Selling, general and administrative (SG&A) expenses increased $249,000, or 29.1%, to $1,104,000 in 2QFY14 from $855,000 in 2QFY13.

The major changes in SG&A expenses for 2QFY14 vs 2QFY13 were:

- Commission expense - increased by $36K, we incurred increased commissions to our Japanese and Chinese dealers as we recorded significantly increased sales in our Asian markets
- Marketing labor costs - increased by $24K, substantive employee time was incurred in conjunction with updating of training material, trade shows and visitation of our Asian dealers
- Travel expenses - increased $33K as the company strategically increased its presence at a number of trade shows and conferences in 2QFY14, in addition, a higher percentage of travel was at international destinations
- Consulting Fees - increased by $44K, we used consultants in 2QF14 for review of contracts and other corporate transactional issues
- Professional fees - increased by $29K, primarily due to costs associated with review of proxy issues and legal issues associated with the company’s amendment of its 2007 Stock Option Plan
- Salaries and wages - Increased $32K due to annual salary review increases and duplicated salaries associated with the transition of the company’s CFO.

*Research and Development*

We incurred approximately $714,000 of research and development costs during 2QFY14. Of this amount, $360,000 was capitalized and $354,000 was expensed. In 2QFY13, we incurred $568,000 of research and development costs, of which $320,000 was capitalized and $248,000 was expensed. The increase of $146,000, or 26%, in total research and development expenditures from 2QFY13 to 2QFY14 was due to an expansion of staff as well as increases in salaries and stock-based compensation increases for existing employees. In addition, the company incurred $26K of costs associated with its COX-2/COX-1 NCE initiative (see NCE discussion in Business section above).

*Other income (expense)*

Net other income in 2QFY14 decreased by $43,000, or 27.7%, to $12,000 in 2QFY14 from $55,000 in 2QFY13. This is due to lower interest income, and lower currency exchange gains in 2QFY14 compared with 2QFY13. In addition 2QFY14 did not include sub-lease income of $15K, which was included in 2QFY13.

*Provision for Income Taxes*

The provision for income taxes decreased by $177,000, or 34.6%, to $334,000 in 2QFY14 from $510,000 in 2QFY13 due to decreased income before taxes. The Company's effective tax rate was 29.2% and differs from statutory rates for the quarter mainly due to R&D tax credits recognized during the period.

*Net Income*

Net income decreased by $252,000, or 23.7%, to $810,000 in 2QFY14 from $1,061,000 in 2QFY13. We attribute this decrease to increased research and development costs and increased operating expenses.

***Comparison of Six Months Ended February 28, 2014 and 2013.***

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):

| | Six Months Ended | | | |
|---|---|---|---|---|
| | 02/28/14 | | 02/28/13 | |
| Net sales | $5,722 | 100.0% | $5,408 | 100.0% |
| Cost of sales | 941 | 16.4 | 885 | 16.3 |
| Gross profit | 4,782 | 83.6 | 4,523 | 83.6 |
| Selling, general and administrative | 2,175 | 38.0 | 1,786 | 33.0 |
| Research and development | 516 | 9.0 | 428 | 7.9 |
| Total operating expenses | 2,691 | 47.0 | 2,214 | 40.9 |
| Income from operations | 2,091 | 36.6 | 2,309 | 42.7 |
| Other income | 45 | 0.7 | 159 | 2.9 |
| Income from operations before taxes | 2,136 | 37.3 | 2,468 | 45.6 |
| (Provision for) income taxes | (641 ) | (11.2) | (819 ) | (15.1) |
| Net income | $1,495 | 26.1% | $1,649 | 30.5% |

*Net Sales*

Net sales increased $314,000 or 5.8%, to $5,722,000 in the first 6 months of fiscal 2014 (“6moFY14”) from $5,408,000 in the first 6 months of fiscal 2013 (“6moFY13)”. The increase in revenues is due to an approximately $512,000 increase in software sales. Service revenues, such as collaboration, analytical studies, and workshop/training activities decreased by $197,000.

*Cost of Sales*

Cost of sales increased by $56,000, or 6.2%, to $941,000 in 6moFY14 from $885,000 in 6moFY13. As a percentage of revenue, cost of sales in 6moFY14 was approximately the same as 6moFY13 increasing by 0.1% to 16.4%. A significant portion of cost of sales for pharmaceutical software products is the systematic amortization of capitalized software development costs. Amortization cost increased approximately $25,000, or 6.9%, in 6moFY14 compared with 6moFY13. Royalty expense, another significant portion of cost of sales, increased approximately $4,000, or 1.1%, in 6moFY14 compared with 6moFY13. We pay a royalty on the core GastroPlus software licenses but not on its optional modules. We also pay royalties to Accelrys on a portion of the ADMET Predictor Metabolism Module.

*Gross Profit*

Gross profit increased $259,000, or 5.7%, to $4,782,000 in 6moFY14 from $4,523,000 in 6moFY13. We attribute this increase to increased revenue outweighing increased cost of sales.

*Selling, General and Administrative Expenses*

Selling, general and administrative (SG&A) expenses increased $389,000, or 21.8%, to $2,175,000 in 6moFY14 from $1,786,000 in 6moFY13.

The major changes in SG&A expenses for 6moFY14 vs 6moFY13 were:

- Commission expense – increased by $66K, we incurred increased commissions to our Japanese and Chinese dealers as we recorded significantly increased sales in our Asian markets
- Marketing labor costs – increased by $21K, substantive employee time was incurred in conjunction with updating of training materials, trade shows and visitation of our Asian dealers
- Travel expenses - increased $49K as the company strategically increased its presence at a number of trade shows and conferences in 6moFY14. In addition, a higher percentage of travel was at international destinations
- Bonus expense - increased by $30K, due to the changes in 2014 compensation plan for the company's Chief Executive Officer (see Notes to Financial statements above)
- Professional fees – increased by $29K, primarily due to costs associated with review of proxy issues and legal issues associated with the company's amendment of its 2007 Stock Option Plan
- Investor relations – increased by $20K, this is due to a change in stock transfer agents which occurred in the 3rd quarter of FY13
- Salaries and wages – increased $88K due to annual salary review increases and some duplicated salaries associated with the transition of the company's CFO. In addition the Life Science staff spent more time on G&A activities in 6moFY14 compared to 6moFY13, resulting in more expense allocated to SG&A

*Research and Development*

We incurred approximately $1,250,000 of research and development costs during 6moFY14. Of this amount, $733,000 was capitalized and $516,000 was expensed. In 6moFY13 we incurred $1,010,000 of research and development costs, of which $582,000 was capitalized and $428,000 was expensed. The increase of $240,000, or 23.7%, in total research and development expenditures from 6moFY13 to 6moFY14 was due to expansion of staff and increases in salaries and stock based compensation for existing employees, in addition the company incurred $26K of costs associated with its NCE initiative (See NCE discussion in Business section above).

*Other income (expense)*

Net other income decreased by $114,000, or 71.7%, to $45,000 in 6moFY14 from $159,000 in 6moFY13. This is due to the lower interest income and lower currency exchange gain in 6moFY14 compared with 6moFY13. In addition 6moFY14 did not include any sub-lease income, while $31K was included in 6moFY13.

*Provision for Income Taxes*

Provision for income taxes decreased by $178,000, or 21.7%, to $641,000 in 6moFY14 from $819,000 in 6moFY13 due to the decrease in income before taxes. The Company's effective tax rate was 30% and differs from statutory rates for the quarter mainly due to R&D tax credits recognized during the period.

*Income from Continuing Operations*

Net income from continuing operations decreased by $154,000, or 9.3%, to $1,495,000 in 6moFY14 from $1,649,000 in 6moFY13. We attribute this decrease to increased research and development costs and increased operating expenses.

**Liquidity and Capital Resources**

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

Item 4. Controls and Procedures

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating disclosure controls and procedures, management recognizes

that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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

Management's Report on Internal Control over Financial Reporting

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

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

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

**Part II. Other Information**

Item 1. Legal Proceedings

The Company is not a party to any legal proceedings and is not aware of any pending legal proceedings of any kind.

Item 1A. Risk Factors

Not applicable.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

| EXHIBIT NUMBER | DESCRIPTION |
|---|---|
| 3.1 | Articles of Incorporation of the Company. (5) |
| 3.2 | Amended and Restated Bylaws of the Company. (5) |
| 4.1 | Articles of Incorporation of the Company. (incorporated by reference to Exhibit 3.1 hereof) |
| 4.2 | Bylaws of the Company. (incorporated by reference to Exhibit 3.2 hereof) |
| 4.3 | Form of Common Stock Certificate (1) |
| 4.4 | Share Exchange Agreement (1) |
| 10.1 | The Company's 1996 Stock Option Plan (the "Option Plan") and forms of agreements relating thereto (1) |
| 10.2 | Exclusive License Software Agreement by and between the Company and Therapeutic Systems Research Laboratories dated June 30, 1997. (2) |
| 10.3 | The Company's 2007 Stock Option Plan. (3) |
| 10.4 | Notice of Election to Extend Term of Lease by and between the Company and Crest Development LLC formerly Freeway Ventures LLC, dated July 29, 2010.(4) |
| 10.5 | Employment Agreement by and between the Company and Walter S. Woltosz, dated as of July 22, 2011. (5) (†) |
| 10.6 | Employment Agreement by and between the Company and Walter S. Woltosz, dated as of August 22, 2013. (6) (†) |
| 10.3 | The Company's Amended 2007 Stock Option Plan. (7). |
| 31.1 | Section 302 – Certification of the Principal Executive Officer. (7) |
| 31.2 | Section 302 – Certification of the Principal Financial Officer. (7) |
| 32.1 | Section 906 – Certification of the Chief Executive Office and Chief Financial Officer. (7) |
| 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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(1) Incorporated by reference to the Company's Registration Statement on Form SB-2 (Registration No. 333-6680) filed on March 25, 1997.

(2) Incorporated by reference to the Company's Form 10-KSB for the fiscal year ended August 31, 1997.

(3) Incorporated by reference to the Company's Form 10-K for the fiscal year ended August 31, 2009.

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

(5) Incorporated by reference to the Company's Form 10-K for the fiscal year ended August 31, 2011.

(6) Incorporated by reference to the Company's Form 8-K filed September 22, 2011.

(7) Filed herewith

**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 April 9, 2014.

Simulations Plus, Inc.

Date: April 9, 2014 By: /s/ *John R Kneisel*
John R. Kneisel
Chief Financial Officer

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