

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the quarterly period ended October 31, 2013

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: 0-17085

**PEREGRINE PHARMACEUTICALS, INC.**

*(Exact name of Registrant as specified in its charter)*

**Delaware**

*(State or other jurisdiction of  
incorporation or organization)*

**95-3698422**

*(I.R.S. Employer  
Identification No.)*

**14282 Franklin Avenue, Tustin, California**

*(Address of principal executive offices)*

**92780-7017**

*(Zip Code)*

**(714) 508-6000**

*(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  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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

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

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer

Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

As of December 6, 2013, there were 160,325,891 shares of common stock, \$0.001 par value, outstanding.

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**PEREGRINE PHARMACEUTICALS, INC.**  
**TABLE OF CONTENTS**

	Page No.
PART I - FINANCIAL INFORMATION	1
Item 1. Consolidated Financial Statements.	1
Item 2. Management’s Discussion and Analysis of Financial Condition And Results of Operations.	15
Item 3. Quantitative and Qualitative Disclosures About Market Risk.	25
Item 4. Controls And Procedures.	26
PART II - OTHER INFORMATION	26
Item 1. Legal Proceedings.	26
Item 1A. Risk Factors.	27
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.	43
Item 3. Defaults Upon Senior Securities.	43
Item 4. Mine Safety Disclosures.	43
Item 5. Other Information.	43
Item 6. Exhibits.	43
SIGNATURES	44

*The terms “we,” “us,” “our,” “the Company,” and “Peregrine,” as used in this Quarterly Report on Form 10-Q refers to Peregrine Pharmaceuticals, Inc. and its wholly owned subsidiary, Avid Bioservices, Inc.*

**PART I - FINANCIAL INFORMATION**

**ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS.**

**PEREGRINE PHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

	<b>OCTOBER 31, 2013</b>	<b>APRIL 30, 2013</b>
	<i>Unaudited</i>	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 44,443,000	\$ 35,204,000
Trade and other receivables, net	1,936,000	1,662,000
Inventories	4,033,000	4,339,000
Prepaid expenses and other current assets, net	874,000	709,000
Total current assets	<u>51,286,000</u>	<u>41,914,000</u>
Property and equipment, net	2,315,000	2,678,000
Other assets	1,506,000	466,000
<b>TOTAL ASSETS</b>	<b><u>\$ 55,107,000</u></b>	<b><u>\$ 45,058,000</u></b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 2,371,000	\$ 2,821,000
Accrued clinical trial and related fees	1,029,000	930,000
Accrued payroll and related costs	3,152,000	3,582,000
Deferred revenue, current portion	3,468,000	4,171,000
Customer deposits	7,658,000	8,059,000
Other current liabilities	1,089,000	998,000
Total current liabilities	<u>18,767,000</u>	<u>20,561,000</u>
Deferred revenue, less current portion	292,000	292,000
Other long-term liabilities	399,000	445,000
Commitments and contingencies (Note 11)		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock-\$0.001 par value; authorized 5,000,000 shares; non-voting; nil shares outstanding	-	-
Common stock-\$0.001 par value; authorized 325,000,000 shares; outstanding - 160,248,742 and 143,768,946, respectively	160,000	143,000
Additional paid-in capital	418,783,000	391,521,000
Accumulated deficit	(383,294,000)	(367,904,000)
Total stockholders' equity	<u>35,649,000</u>	<u>23,760,000</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b><u>\$ 55,107,000</u></b>	<b><u>\$ 45,058,000</u></b>

See accompanying notes to condensed consolidated financial statements.

PEREGRINE PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	THREE MONTHS ENDED OCTOBER 31,		SIX MONTHS ENDED OCTOBER 31,	
	2013	2012	2013	2012
	<i>Unaudited</i>	<i>Unaudited</i>	<i>Unaudited</i>	<i>Unaudited</i>
<b>REVENUES:</b>				
Contract manufacturing revenue	\$ 7,354,000	\$ 6,061,000	\$ 11,935,000	\$ 10,196,000
License revenue	–	78,000	107,000	194,000
Total revenues	<u>7,354,000</u>	<u>6,139,000</u>	<u>12,042,000</u>	<u>10,390,000</u>
<b>COSTS AND EXPENSES:</b>				
Cost of contract manufacturing	4,195,000	3,703,000	6,865,000	5,727,000
Research and development	6,957,000	6,053,000	12,261,000	13,034,000
Selling, general and administrative	4,016,000	3,440,000	8,350,000	6,357,000
Total costs and expenses	<u>15,168,000</u>	<u>13,196,000</u>	<u>27,476,000</u>	<u>25,118,000</u>
<b>LOSS FROM OPERATIONS</b>	<u>(7,814,000)</u>	<u>(7,057,000)</u>	<u>(15,434,000)</u>	<u>(14,728,000)</u>
<b>OTHER INCOME (EXPENSE):</b>				
Interest and other income	24,000	44,000	45,000	52,000
Interest and other expense	–	(44,000)	(1,000)	(45,000)
Loss on early extinguishment of debt	–	(1,696,000)	–	(1,696,000)
<b>NET LOSS</b>	<u>\$ (7,790,000)</u>	<u>\$ (8,753,000)</u>	<u>\$ (15,390,000)</u>	<u>\$ (16,417,000)</u>
<b>COMPREHENSIVE LOSS</b>	<u>\$ (7,790,000)</u>	<u>\$ (8,753,000)</u>	<u>\$ (15,390,000)</u>	<u>\$ (16,417,000)</u>
<b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:</b>				
Basic and Diluted	<u>156,948,226</u>	<u>109,405,778</u>	<u>153,170,928</u>	<u>106,344,857</u>
<b>BASIC AND DILUTED LOSS PER COMMON SHARE</b>	<u>\$ (0.05)</u>	<u>\$ (0.08)</u>	<u>\$ (0.10)</u>	<u>\$ (0.15)</u>

See accompanying notes to condensed consolidated financial statements.

PEREGRINE PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	SIX MONTHS ENDED OCTOBER 31,	
	2013	2012
	<i>Unaudited</i>	<i>Unaudited</i>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (15,390,000)	\$ (16,417,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	3,313,000	1,291,000
Depreciation and amortization	493,000	526,000
Loss on early extinguishment of debt	–	1,696,000
Changes in operating assets and liabilities:		
Trade and other receivables, net	(274,000)	33,000
Inventories	306,000	(1,815,000)
Prepaid expenses and other current assets, net	(165,000)	(90,000)
Accounts payable	(527,000)	(316,000)
Accrued clinical trial and related fees	99,000	(553,000)
Accrued payroll and related expenses	(430,000)	(74,000)
Deferred revenue	(703,000)	2,414,000
Customer deposits	(401,000)	3,635,000
Other accrued expenses and current liabilities	115,000	70,000
Other long-term liabilities	(46,000)	(58,000)
Net cash used in operating activities	(13,610,000)	(9,658,000)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Property and equipment acquisitions	(53,000)	(309,000)
Increase in other assets	(1,040,000)	(201,000)
Net cash used in investing activities	(1,093,000)	(510,000)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock, net of issuance costs of \$722,000 and \$620,000, respectively	23,555,000	17,595,000
Proceeds from issuance of notes payable, net of issuance costs of \$251,000	–	14,749,000
Proceeds from issuance of common stock under Employee Stock Purchase Plan	282,000	214,000
Proceeds from exercise of stock options	129,000	34,000
Principal payments on notes payable	–	(15,000,000)
Payment of final fee on notes payable	–	(975,000)
Principal payments on capital leases	(24,000)	(39,000)
Net cash provided by financing activities	23,942,000	16,578,000
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>9,239,000</b>	<b>6,410,000</b>
<b>CASH AND CASH EQUIVALENTS, beginning of period</b>	<b>35,204,000</b>	<b>18,033,000</b>
<b>CASH AND CASH EQUIVALENTS, end of period</b>	<b>\$ 44,443,000</b>	<b>\$ 24,443,000</b>
<b>SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:</b>		
Accounts payable for purchase of property	\$ 77,000	\$ –
Fair market value of warrants issued in connection with notes payable	\$ –	\$ 470,000

See accompanying notes to condensed consolidated financial statements.

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE SIX MONTHS ENDED OCTOBER 31, 2013 (unaudited)**

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1. ORGANIZATION AND BUSINESS

Peregrine Pharmaceuticals, Inc. (“Peregrine”, “we”, “us”, “our” or the “Company”) is a biopharmaceutical company with a portfolio of innovative monoclonal antibodies in clinical trials focused on the treatment and diagnosis of cancer. We are advancing our lead immunotherapy candidate, baviximab, into Phase III development for the treatment of second-line non-small cell lung cancer (the “SUNRISE trial”) while also seeking a licensing or funding partner to further advance Cotara into Phase III development for the treatment of brain cancer. In addition, we are evaluating our lead molecular imaging agent, 124I-PGN650, in an exploratory clinical trial for the imaging of multiple solid tumor types. Peregrine also has in-house manufacturing capabilities through its wholly-owned subsidiary Avid Bioservices, Inc. (“Avid”), a contract manufacturing organization that provides development and biomanufacturing services for Peregrine and its third-party clients.

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 quarterly reports 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 the Company’s Annual Report on Form 10-K for the year ended April 30, 2013. The condensed consolidated balance sheet at April 30, 2013, has been derived from audited financial statements at that date. 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. Results of operations for interim periods covered by this quarterly report on Form 10-Q may not necessarily be indicative of results of operations for the full fiscal year.

The interim unaudited condensed consolidated financial statements include the accounts of Peregrine and Avid. All intercompany accounts and transactions have been eliminated in the interim unaudited condensed consolidated financial statements.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts, as well as disclosures of commitments and contingencies in the financial statements and accompanying notes. Actual results could differ from those estimates.

**Adoption of Recent Accounting Pronouncements**

Effective May 1, 2013, we adopted Financial Accounting Standards Board’s (“FASB”) Accounting Standards Update (“ASU”) No. 2013-02, Other Comprehensive Income (Topic 220): *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*. ASU No. 2013-02 does not change the current requirements for reporting net income or other comprehensive income in financial statements, however, it does require an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amounts are required to be reclassified in their entirety to net income. For other amounts that are not required to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference to other disclosures that provide additional detail about those amounts. The adoption ASU No. 2013-02 did not have a material impact on our consolidated financial statements.

**Pending Adoption of Recent Accounting Pronouncements**

In July 2013, the FASB issued ASU No. 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*. ASU No. 2013-11 requires entities to present in the financial statements an unrecognized tax benefit, or a portion of an unrecognized tax benefit as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward except to the extent such items are not available or not intended to be used at the reporting date to settle any additional income taxes that would result from the disallowance of a tax position. In such instances, the unrecognized tax benefit is required to be presented in the financial statements as a liability and not be combined with deferred tax assets. This guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, which will be our fiscal year 2015 (or May 1, 2014). We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE SIX MONTHS ENDED OCTOBER 31, 2013 (unaudited) (continued)**

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**Liquidity and Financial Condition**

At October 31, 2013, we had \$44,443,000 in cash and cash equivalents. We have expended substantial funds on the research and development of our product candidates, and funding the operations of Avid. As a result, we have historically experienced negative cash flows from operations since our inception and we expect negative cash flows from operations to continue in the foreseeable future. Our net loss incurred during the six-month period ended October 31, 2013 amounted to \$15,390,000 and our net losses incurred during the past three fiscal years ended April 30, 2013, 2012 and 2011, amounted to \$29,780,000, \$42,119,000, and \$34,151,000, respectively. Therefore, unless and until we are able to generate sufficient revenues from Avid's contract manufacturing services and/or from the sale and/or licensing of our products under development, we expect such losses to continue in the foreseeable future.

Therefore, our ability to continue to fund our clinical trials and development efforts is highly dependent on the amount of cash and cash equivalents on hand combined with our ability to raise additional capital to support our future operations through one or more methods, including but not limited to, issuing additional equity or debt.

Historically, we have funded a significant portion of our operations through the issuance of equity. During the six months ended October 31, 2013, we raised \$24,277,000 in aggregate gross proceeds under an At Market Sales Issuance Agreement (Note 7). With these proceeds, we currently estimate that we have sufficient cash resources to meet our anticipated cash needs to fund our operations through at least September 2014 based on our current projections, which includes projected costs associated with our Phase III SUNRISE trial, projected cash inflows under signed contracts with existing customers of Avid and assuming we raise no additional capital from the capital markets or other potential sources.

However, our ability to continue to fund our clinical trials and development efforts in future years, including costs to fund our Phase III SUNRISE trial beyond September 2014, is highly dependent on our ability to raise additional capital to support our future operations through one or more methods, including but not limited to, financing our operations through the issuance of equity, securing new funding through the issuance of debt, licensing or partnering our products in development, or increasing revenue from our wholly-owned subsidiary, Avid. While we will continue to explore these potential opportunities, we may not be successful in securing debt financing, licensing or partnering our products in development, or generating additional revenue from Avid to complete the research, development, and clinical testing of our product candidates. Even if we are successful in obtaining debt financing, it may involve restrictive covenants on the operation of our business and require significant interest payments.

With respect to our ability to raise additional capital from the issuance of equity, as of October 31, 2013, we have an effective shelf registration statement on Form S-3, under which we may issue, from time to time, in one or more offerings, shares of our common stock for gross proceeds of up to \$112,351,000. However, our ability to raise additional capital in the equity markets is dependent on a number of factors, including, but not limited to, the market demand for our common stock. The market demand or liquidity of our common stock is subject to a number of risks and uncertainties, including but not limited to, negative economic conditions, adverse market conditions, adverse clinical trial results and significant delays in one or more clinical trials. If our ability to access the capital markets becomes severely restricted, it could have a negative impact on our business plans, including our clinical trial programs and other research and development activities. In addition, even if we are able to raise additional capital, it may not be at a price or on terms that are favorable to us.

**Revenue Recognition**

We currently derive revenue from two sources: (i) contract manufacturing services provided by Avid, and (ii) licensing revenues related to agreements associated with Peregrine's technologies under development.

We recognize revenue in accordance with the authoritative guidance for revenue recognition. We recognize revenue when all of the following criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery (or passage of title) has occurred or services have been rendered, (iii) the seller's price to the buyer is fixed or determinable, and (iv) collectability is reasonably assured. We also comply with the authoritative guidance for revenue recognition regarding arrangements with multiple deliverables.

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE SIX MONTHS ENDED OCTOBER 31, 2013 (unaudited) (continued)**

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*Contract Manufacturing Revenue*

Revenue associated with contract manufacturing services provided by Avid is recognized once the service has been rendered and/or upon shipment (or passage of title) of the product to the customer. On occasion, we recognize revenue on a “bill-and-hold” basis in accordance with the authoritative guidance. Under “bill-and-hold” arrangements, revenue is recognized once the product is complete and ready for shipment, title and risk of loss has passed to the customer, management receives a written request from the customer for “bill-and-hold” treatment, the product is segregated from other inventory, and no further performance obligations exist.

In addition, we also follow the authoritative guidance when reporting revenue as gross when we act as a principal versus reporting revenue as net when we act as an agent. For transactions in which we act as a principal, have discretion to choose suppliers, bear credit and inventory risk and perform a substantive part of the services, revenue is recorded at the gross amount billed to a customer and costs associated with these reimbursements are reflected as a component of cost of sales for contract manufacturing services.

Any amounts received prior to satisfying our revenue recognition criteria are recorded as deferred revenue in the accompanying interim unaudited condensed consolidated financial statements. We also record a provision for estimated contract losses, if any, in the period in which they are determined.

*License Revenue*

Revenue associated with licensing agreements primarily consists of non-refundable upfront license fees, non-refundable annual license fees and milestone payments. Non-refundable upfront license fees received under license agreements, whereby continued performance or future obligations are considered inconsequential to the relevant license technology, are recognized as revenue upon delivery of the technology. If a licensing agreement has multiple elements, we analyze each element of our licensing agreements and consider a variety of factors in determining the appropriate method of revenue recognition of each element.

*Multiple Element Arrangements.* Prior to the adoption of ASU No. 2009-13 on May 1, 2011, if a license agreement has multiple element arrangements, we analyze and determine whether the deliverables, which often include performance obligations, can be separated or whether they must be accounted for as a single unit of accounting in accordance with the authoritative guidance. Under multiple element arrangements, we recognize revenue for delivered elements only when the delivered element has stand-alone value and we have objective and reliable evidence of fair value for each undelivered element. If the fair value of any undelivered element included in a multiple element arrangement cannot be objectively determined, the arrangement would then be accounted for as a single unit of accounting, and revenue is recognized over the estimated period of when the performance obligation(s) are performed.

In addition, under certain circumstances, when there is objective and reliable evidence of the fair value of the undelivered items in an arrangement, but no such evidence for the delivered items, we utilize the residual method to allocate the consideration received under the arrangement. Under the residual method, the amount of consideration allocated to delivered items equals the total arrangement consideration less the aggregate fair value of the undelivered items, and revenue is recognized upon delivery of the undelivered items based on the relative fair value of the undelivered items.

For new licensing agreements or material modifications of existing licensing agreements entered into after May 1, 2011, we follow the provisions of ASU No. 2009-13. If a licensing agreement includes multiple elements, we identify which deliverables represent separate units of accounting, and then determine how the arrangement consideration should be allocated among the separate units of accounting, which may require the use of significant judgment.



**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE SIX MONTHS ENDED OCTOBER 31, 2013 (unaudited) (continued)**

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If a licensing agreement includes multiple elements, a delivered item is considered a separate unit of accounting if both of the following criteria are met:

1. The delivered item has value to the licensing partner on a standalone basis based on the consideration of the relevant facts and circumstances for each agreement;
2. If the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the Company's control.

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 arrangement consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under any agreement.

*Milestone Payments.* Effective May 1, 2011, we adopted on a prospective basis the Milestone Method under ASU No. 2010-17 for new licensing agreements or material modifications of existing licensing agreements entered into after May 1, 2011. Under the Milestone Method, we recognize consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following criteria:

1. The consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone;
2. The consideration relates solely to past performance; and
3. The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the Company.

The provisions of ASU No. 2010-17 do not apply to contingent consideration for which payment is either contingent solely upon the passage of time or the result of a counterparty's performance. We will assess the nature of, and appropriate accounting for, these payments on a case-by-case basis in accordance with the applicable authoritative guidance for revenue recognition.

Any amounts received prior to satisfying our revenue recognition criteria are recorded as deferred revenue in the accompanying interim unaudited condensed consolidated financial statements.

#### **Fair Value Measurements**

We determine fair value measurements in accordance with the authoritative guidance for fair value measurements and disclosures for all assets and liabilities within the scope of this guidance. This guidance, which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The guidance prioritizes the inputs used in measuring fair value into the following hierarchy:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Observable inputs other than quoted prices included in Level 1, such as assets or liabilities whose values are based on quoted market prices in markets where trading occurs infrequently or whose values are based on quoted prices of instruments with similar attributes in active markets.
- Level 3 – Unobservable inputs that are supported by little or no market activity and significant to the overall fair value measurement.

As of October 31, 2013 and April 30, 2013, we do not have any Level 2 or Level 3 financial assets or liabilities and our cash and cash equivalents are carried at fair value based on quoted market prices for identical securities (Level 1 input).

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE SIX MONTHS ENDED OCTOBER 31, 2013 (unaudited) (continued)**

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**Customer Deposits**

Customer deposits primarily represent advance billings and/or payments received from Avid's third-party customers prior to the initiation of contract manufacturing services.

**Research and Development Expenses**

Research and development costs are charged to expense when incurred in accordance with the authoritative guidance for research and development costs. Research and development expenses primarily include (i) payroll and related costs associated with research and development personnel, (ii) share-based compensation expense associated with share-based awards granted to research and development personnel, (iii) costs related to clinical and preclinical testing of our technologies under development, (iv) costs to develop and manufacture the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses, (v) expenses for research services provided by universities and contract laboratories, including sponsored research funding, and (vi) other research and development expenses.

**Accrued Clinical Trial and Related Fees**

We accrue clinical trial and related fees based on work performed in connection with advancing our clinical trials, which relies on estimates and/or representations from clinical research organizations ("CROs"), hospitals, consultants and other clinical trial related vendors. We maintain regular communication with our vendors, including our CROs, and gauge the reasonableness of estimates provided. However, actual clinical trial costs may differ from estimated clinical trial costs and are adjusted for in the period in which they become known. There were no material adjustments for a change in estimate to research and development expenses in the accompanying interim unaudited condensed consolidated financial statements for the three and six months ended October 31, 2013 and 2012.

**Share-based Compensation**

We account for stock options and other share-based awards granted under our equity compensation plans in accordance with the authoritative guidance for share-based compensation. The estimated fair value of share-based payments to employees in exchange for services is measured at the grant date, using a fair value based method, and is recognized as expense on a straight-line basis over the requisite service periods. Share-based compensation expense recognized during the period is based on the value of the portion of the share-based payment that is ultimately expected to vest during the period.

In addition, we periodically grant stock options and other share-based awards to non-employee consultants, which we account for in accordance with the authoritative guidance for share-based compensation. The cost of non-employee services received in exchange for share-based awards are measured based on either the fair value of the consideration received or the fair value of the share-based award issued, whichever is more reliably measurable. In addition, guidance requires share-based compensation related to unvested options and awards issued to non-employees to be recalculated at the end of each reporting period based upon the fair market value on that date until the share-based award has vested, and any adjustment to share-based compensation resulting from the re-measurement is recognized in the current period. See Note 8 for further discussion regarding share-based compensation.

**Basic and Dilutive Net Loss Per Common Share**

Basic net loss per common share is computed by dividing our net loss by the weighted average number of common shares outstanding during the period excluding the dilutive effects of stock options, common shares expected to be issued under our employee stock purchase plan, and warrants in accordance with the authoritative guidance. Diluted net loss per common share is computed by dividing the net loss by the sum of the weighted average number of common shares outstanding during the period plus the potential dilutive effects of stock options, common shares expected to be issued under our employee stock purchase plan, and warrants outstanding during the period calculated in accordance with the treasury stock method, but are excluded if their effect is anti-dilutive. Because the impact of options, common shares expected to be issued under our employee stock purchase plan, and warrants are anti-dilutive during periods of net loss, there was no difference between basic and diluted loss per share amounts for the three and six months ended October 31, 2013 and 2012.

The calculation of weighted average diluted shares outstanding excludes the dilutive effect of outstanding stock options, common shares expected to be issued under our employee stock purchase plan, and warrants, to purchase up to an aggregate of 3,700,172 and 4,041,090 shares of common stock for the three and six months ended October 31, 2013, respectively, 4,824,231 and 3,472,288 shares of common stock for the three and six months ended October 31, 2012, respectively, since their impact are anti-dilutive during periods of net loss.

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE SIX MONTHS ENDED OCTOBER 31, 2013 (unaudited) (continued)**

The calculation of weighted average diluted shares outstanding also excludes weighted average outstanding stock options and warrants to purchase up to an aggregate of 9,832,839 and 6,025,221 shares of common stock for the three and six months ended October 31, 2013, respectively, and 4,884,707 and 5,728,569 shares of common stock for the three and six months ended October 31, 2012, respectively, as their exercise prices were greater than the average market price of our common stock during the respective periods, resulting in an anti-dilutive effect.

**3. TRADE AND OTHER RECEIVABLES**

Trade and other receivables, net, consists of the following at October 31, 2013 and April 30, 2013:

	<b>October 31, 2013</b>	<b>April 30, 2013</b>
Trade receivables <sup>(1)</sup>	\$ 1,931,000	\$ 1,642,000
Other receivables, net	5,000	20,000
Trade and other receivables, net	<u>\$ 1,936,000</u>	<u>\$ 1,662,000</u>

(1) Represents amounts billed for contract manufacturing services provided by Avid.

We continually monitor our allowance for doubtful accounts for all receivables. We apply judgment in assessing the ultimate realization of our receivables and we estimate an allowance for doubtful accounts based on various factors, such as, the aging of accounts receivable balances, historical experience, and the financial condition of our customers. Based on our analysis of our receivables as of October 31, 2013 and April 30, 2013, we determined an allowance for doubtful accounts of \$13,000 and \$16,000, respectively, was necessary with respect to our other receivables, and no allowance was necessary with respect to our trade receivables.

**4. PROPERTY AND EQUIPMENT**

Property and equipment, net, consists of the following at October 31, 2013 and April 30, 2013:

	<b>October 31, 2013</b>	<b>April 30, 2013</b>
Leasehold improvements	\$ 1,453,000	\$ 1,383,000
Laboratory equipment	5,493,000	5,441,000
Furniture, fixtures, office equipment and software	2,635,000	2,627,000
	<u>9,581,000</u>	<u>9,451,000</u>
Less accumulated depreciation and amortization	(7,266,000)	(6,773,000)
Property and equipment, net	<u>\$ 2,315,000</u>	<u>\$ 2,678,000</u>

Depreciation and amortization expense for three and six months ended October 31, 2013 was \$236,000 and \$493,000, respectively, and \$266,000 and \$526,000 for the three and six months ended October 31, 2012, respectively.

**5. INVENTORIES**

Inventories are stated at the lower of cost or market and primarily include raw materials, direct labor and overhead costs (work-in-process) associated with our wholly-owned subsidiary, Avid. Cost is determined by the first-in, first-out method. Inventories consist of the following at October 31, 2013 and April 30, 2013:

	<b>October 31, 2013</b>	<b>April 30, 2013</b>
Raw materials	\$ 2,142,000	\$ 2,169,000
Work-in-process	1,891,000	2,170,000
Total inventories	<u>\$ 4,033,000</u>	<u>\$ 4,339,000</u>

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE SIX MONTHS ENDED OCTOBER 31, 2013 (unaudited) (continued)**

6. NOTE PAYABLE

On August 30, 2012, we entered into a loan and security agreement (the "Loan Agreement") with Oxford Finance LLC, MidCap Financial SBIC LP, and Silicon Valley Bank (collectively, the "Lenders") for up to \$30,000,000 in total funding available in two \$15,000,000 tranches. The Loan Agreement was secured by a first-priority security interest in substantially all of our assets, excluding our intellectual property and our rights under license agreements granting us rights to intellectual property. On August 30, 2012, we received initial funding of \$15,000,000 under the Loan Agreement, excluding debt issuance costs of \$251,000.

On September 24, 2012, we received a written notice of default ("Notice of Default") from the Lenders, with respect to the Loan Agreement. The Notice of Default was triggered by a material adverse change under the Loan Agreement due to our discovery of major discrepancies in treatment group coding by an independent third-party vendor responsible for distribution of blinded investigational product used in our bavituximab Phase IIb second-line NSCLC clinical trial. Pursuant to the terms of the Notice of Default, all amounts due under the Loan Agreement were declared immediately due and payable by the Lenders. On September 25, 2012, we paid the Lenders all obligations declared due and payable under the Loan Agreement, including outstanding principal of \$15,000,000, accrued interest thereon at the Loan Agreement's applicable fixed rate of 7.95% per annum, plus a final payment fee equal to 6.5% of the principal amount funded (or \$975,000), upon which, the Loan Agreement was terminated.

In addition, under the Loan Agreement, we agreed to issue to the Lenders six-year warrants to purchase shares of our common stock upon the funding of each tranche in an amount equal to 4.50% of the amount of such tranche divided by the exercise price as defined in the Loan Agreement. Upon the initial funding under the Loan Agreement, we issued the Lenders warrants to purchase an aggregate of 273,280 shares of our common stock at a per share price of \$2.47, which are exercisable on a cash or cashless basis, and will expire on August 30, 2018. The fair value of the warrants issued was \$470,000 and was calculated using a Black-Scholes valuation model with the following assumptions: risk-free interest rate of 0.87%; expected volatility of 80.20%; expected term of six years; and a dividend yield of 0%. The fair value of the warrants issued was initially recorded as a debt discount with a corresponding increase to additional paid-in capital. As of October 31, 2013, the warrants issued under the Loan Agreement were outstanding and exercisable (Note 9).

Upon the termination of the Loan Agreement, we recorded a loss on the early extinguishment of debt of \$1,696,000, which consisted of the final payment fee of \$975,000, the unamortized debt discount associated with the fair value of the warrants issued to the Lenders of \$470,000, and the unamortized aggregate debt issuance costs of \$251,000. The loss on the early extinguishment of debt is included in the accompanying interim unaudited condensed consolidated statements of operations and comprehensive loss for the three and six months ended October 31, 2012.

7. STOCKHOLDERS' EQUITY

**Sales of Common Stock**

Our ability to continue our clinical trials and development efforts is highly dependent on the amount of cash and cash equivalents on hand combined with our ability to raise additional capital to support our future operations through one or more methods, including but not limited to, issuing additional equity.

With respect to financing our operations through the issuance of equity, on December 27, 2012, we entered into an At Market Sales Issuance Agreement ("December 2012 AMI Agreement") with MLV & Co. LLC ("MLV"), pursuant to which we may sell shares of our common stock through MLV, as agent, for aggregate gross proceeds of up to \$75,000,000, in registered transactions from our shelf registration statement on Form S-3 (File No. 333-180028). During the six months ended October 31, 2013, we sold 15,938,269 shares of common stock at market prices under the December 2012 AMI Agreement for aggregate gross proceeds of \$24,277,000 before deducting commissions and other issuance costs of \$722,000. As of October 31, 2013, aggregate gross proceeds of up to \$37,351,000 remained available under the December 2012 AMI Agreement.

**Shares of Common Stock Authorized and Reserved for Future Issuance**

As of October 31, 2013, we had reserved 29,858,569 additional shares of our common stock, which may be issued under our equity compensation plans and outstanding warrant agreements, excluding shares of common stock that could potentially be issued under our current effective shelf registration statement, as further described in the following table:

	Number of Shares Reserved
Common shares reserved for issuance under outstanding option grants and common shares available for issuance under our stock incentive plans	26,306,989
Common shares reserved for and available for issuance under our Employee Stock Purchase Plan	3,176,777
Common shares issuable upon exercise of outstanding warrants	374,803
Total shares of common stock reserved for issuance	<u>29,858,569</u>

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE SIX MONTHS ENDED OCTOBER 31, 2013 (unaudited) (continued)**

## 8. EQUITY COMPENSATION PLANS

**Stock Incentive Plans**

On October 17, 2013, our stockholders approved an amendment to our 2011 Stock Incentive Plan (the “2011 Plan”) to increase the number of shares of our common stock reserved for issuance under the 2011 Plan from 11,500,000 shares to up to 18,500,000 shares.

As of October 31, 2013, we had an aggregate of 26,306,989 shares of our common stock reserved for issuance under our stock incentive plans, of which, 18,451,688 shares were subject to outstanding options and 7,855,301 shares were available for future grants of share-based awards.

The following summarizes our stock option transaction activity for the six months ended October 31, 2013:

<b>Stock Options</b>	<b>Shares</b>	<b>Weighted Average Exercisable Price</b>
Outstanding, May 1, 2013	15,287,208	\$ 1.84
Granted	4,441,412	\$ 1.42
Exercised	(179,745)	\$ 0.72
Canceled or expired	(1,097,187)	\$ 4.99
Outstanding, October 31, 2013	18,451,688	\$ 1.56

The following summarizes our restricted stock award transaction activity for the six months ended October 31, 2013:

<b>Restricted Stock</b>	<b>Shares</b>	<b>Weighted Average Grant Date Fair Value</b>
Unvested, May 1, 2013	–	\$ –
Granted	100,000	\$ 1.39
Vested	(100,000)	\$ 1.39
Canceled or expired	–	\$ –
Unvested, October 31, 2013	–	\$ –

**Employee Stock Purchase Plan**

We have reserved a total of 5,000,000 shares of common stock to be purchased under our 2010 Employee Stock Purchase Plan (the “2010 ESPP”), of which 3,176,777 shares of common stock remain available for purchase as of October 31, 2013. Under the 2010 ESPP, we will sell shares to participants at a price equal to the lesser of 85% of the fair market value of stock at the (i) beginning of a six-month offering period or (ii) at the end of the six-month offering period. The 2010 ESPP provides for two six-month offering periods each year; the first offering period will begin on the first trading day on or after each November 1; the second offering period will begin on the first trading day on or after each May 1. During the six months ended October 31, 2013, 261,782 shares of our common stock were purchased under the 2010 ESPP at a purchase price per share of \$1.08.

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE SIX MONTHS ENDED OCTOBER 31, 2013 (unaudited) (continued)**

**Share-Based Compensation**

Total share-based compensation expense for the three and six-month periods ended October 31, 2013 and 2012 are included in the accompanying interim unaudited condensed consolidated statements of operations and comprehensive loss as follows:

	Three Months Ended October 31,		Six Months Ended October 31,	
	2013	2012	2013	2012
Cost of contract manufacturing	\$ 16,000	\$ 9,000	\$ 40,000	\$ 18,000
Research and development	721,000	289,000	1,462,000	612,000
Selling, general and administrative	983,000	331,000	1,811,000	661,000
Total	<u>\$ 1,720,000</u>	<u>\$ 629,000</u>	<u>\$ 3,313,000</u>	<u>\$ 1,291,000</u>
Share-based compensation from:				
Stock options	\$ 1,506,000	\$ 584,000	\$ 3,009,000	\$ 1,199,000
Restricted stock awards	139,000	—	139,000	—
Employee stock purchase plan	75,000	45,000	165,000	92,000
	<u>\$ 1,720,000</u>	<u>\$ 629,000</u>	<u>\$ 3,313,000</u>	<u>\$ 1,291,000</u>

As of October 31, 2013, the total estimated unrecognized compensation cost related to non-vested stock options was \$6,749,000. This cost is expected to be recognized over a weighted average vesting period of 1.29 years based on current assumptions.

9. WARRANTS

No warrants were granted or exercised during the three and six months ended October 31, 2013. As of October 31, 2013, the following warrants to purchase an aggregate of 374,803 shares of our common stock were outstanding:

Date Issued	Warrants Outstanding	Exercise Price Per Share	Expiration Date
December 19, 2008	101,523	\$1.4775	December 19, 2013
August 30, 2012 (Note 6)	273,280	\$2.4700	August 30, 2018
Total Warrants Outstanding	<u>374,803</u>		

10. SEGMENT REPORTING

Our business is organized into two reportable operating segments and both operate in the U.S. Peregrine is engaged in the research and development of monoclonal antibodies for the treatment and diagnosis of cancer. Avid is engaged in providing contract manufacturing services for Peregrine and third-party customers on a fee-for-service basis.

The accounting policies of the operating segments are the same as those described in Note 2. We evaluate the performance of our contract manufacturing services segment based on gross profit or loss from third-party customers. However, our products in the research and development segment are not evaluated based on gross profit or loss, but rather based on scientific progress of the technologies. As such, gross profit or loss is only provided for our contract manufacturing services segment in the below table. All revenues shown below are derived from transactions with third-party customers.

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE SIX MONTHS ENDED OCTOBER 31, 2013 (unaudited) (continued)**

Segment information for the three and six-month periods is summarized as follows:

	<b>Three Months Ended October 31,</b>		<b>Six Months Ended October 31,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
Contract manufacturing services revenue	\$ 7,354,000	\$ 6,061,000	\$ 11,935,000	\$ 10,196,000
Cost of contract manufacturing services	4,195,000	3,703,000	6,865,000	5,727,000
Gross profit	3,159,000	2,358,000	5,070,000	4,469,000
Revenue from products in research and development	–	78,000	107,000	194,000
Research and development expense	(6,957,000)	(6,053,000)	(12,261,000)	(13,034,000)
Selling, general and administrative expense	(4,016,000)	(3,440,000)	(8,350,000)	(6,357,000)
Other income (expense), net	24,000	–	44,000	7,000
Loss on early extinguishment of debt	–	(1,696,000)	–	(1,696,000)
Net loss	<u>\$ (7,790,000)</u>	<u>\$ (8,753,000)</u>	<u>\$ (15,390,000)</u>	<u>\$ (16,417,000)</u>

Revenue generated from our contract manufacturing services segment was derived from a limited number of customers. The percentages below represent revenue derived from each customer as a percentage of total contract manufacturing services revenue:

	<b>Three Months Ended October 31,</b>		<b>Six Months Ended October 31,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
United States (customer A)	85%	97%	88%	90%
United States (customer B)	13	–	8	–
Other customers	2	3	4	10
Total	<u>100%</u>	<u>100%</u>	<u>100%</u>	<u>100%</u>

Revenue generated from our products in our research and development segment during the three and six months ended October 31, 2013 and 2012 is directly related to license revenue recognized under licensing agreements with an unrelated entity.

#### 11. COMMITMENTS AND CONTINGENCIES

In the ordinary course of business, we are at times subject to various legal proceedings and disputes. Except as set forth below, we currently are not aware of any material litigation or other dispute nor, to management's knowledge, is any litigation or other proceeding threatened against us that collectively is expected to have a material adverse effect on our consolidated cash flows, financial condition or results of operations.

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE SIX MONTHS ENDED OCTOBER 31, 2013 (unaudited) (continued)**

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*Securities Class Action Lawsuit*

On September 28, 2012, three complaints were filed in the U.S. District Court for the Central District of California against us and certain of our executive officers and one consultant (collectively, the “Defendants”) on behalf of certain purchasers of our common stock. The complaints have been brought as purported stockholder class actions, and, in general, include allegations that Defendants violated (i) Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder and (ii) Section 20(a) of the Exchange Act, by making materially false and misleading statements regarding the interim results of our bavituximab Phase II second-line NSCLC trial, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief. On November 27, 2012, four prospective lead plaintiffs filed motions to consolidate, appoint a lead plaintiff and appoint lead counsel. On February 5, 2013, the court consolidated the related actions with the low-numbered case (captioned *Anderson v. Peregrine Pharmaceuticals, Inc., et al.*, Case No. 12-cv-1647-PSG (FMOx)), appointed James T. Fahey as lead plaintiff, and appointed Mr. Fahey’s counsel as lead counsel. The lead plaintiff filed an amended consolidated complaint on April 15, 2013. On June 14, 2013, Defendants moved to dismiss the amended consolidated complaint. On July 15, 2013, lead plaintiff filed an opposition to Defendants’ motion to dismiss and separately moved to strike certain exhibits attached to Defendants’ motion. On August 19, 2013 the court held a hearing on Defendants’ motion to dismiss and on lead plaintiff’s motion to strike. On August 23, 2013, the court issued its order granting Defendants’ motion to dismiss and denying lead plaintiff’s motion to strike. In its order, the court gave lead plaintiff leave to amend his complaint on or before September 16, 2013. On September 16, 2013 lead plaintiff filed his first amended complaint. On October 3, 2013, Defendants’ filed a motion to dismiss the first amended complaint. Briefing on that motion concluded in early November 2013 and, on November 22, 2013, the court issued an order granting Defendants’ motion to dismiss the first amended complaint. The court again granted lead plaintiff leave to file an amended complaint, which is due no later than January 22, 2014. We believe that the class action lawsuit is without merit and intend to vigorously defend the action, including seeking dismissal of any amended complaint. Due to the early stage of the proceeding, we believe that the probability of an unfavorable outcome or loss related to the proceeding and an estimate of the amount or range of loss related to the claims, if any, from an unfavorable outcome is not determinable at this time.

*Derivative Litigation*

On May 9, 2013, an alleged shareholder filed, purportedly on behalf of the Company, a derivative lawsuit, captioned *Roy v. Steven W. King, et al.*, Case No. 13-cv-0741-PSG (RNBx), in the U.S. District Court for the Central District of California against certain of our executive officers and directors. The complaint asserts claims for breach of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment arising from substantially similar factual allegations as those asserted in the consolidated securities class action lawsuit, described above (the “Securities Class Action”). This case was subsequently transferred to the same court and judge handling the Securities Class Action lawsuit. On May 31, 2013, the judge issued an order staying this derivative litigation pending the final resolution of defendants’ motions to dismiss in the Securities Class Action.

On October 10, 2013, a derivative and class action complaint, captioned *Michaeli v. Steven W. King, et al.*, C.A. No. 8994-VCL, was filed in the Court of Chancery of the State of Delaware against certain of our executive officers and directors. The complaint alleges that the Company’s directors and executives breached their respective fiduciary duties in connection with certain purportedly improper compensation decisions made by the Company’s Board of Directors during the past three fiscal years, including: (i) the grant of a stock option to Mr. King on May 4, 2012; (ii) the non-routine broad-based stock option grant to the Company’s directors, executives, all other employees and certain consultants on December 27, 2012; and (iii) the payment, during the past three fiscal years, of compensation to the Company’s non-employee directors. In addition, the complaint alleges that the Company’s directors breached their fiduciary duty of candor by filing and seeking stockholder action on the basis of an allegedly materially false and misleading proxy statement for the Company’s 2013 annual meeting of stockholders. On December 2, 2013, the Chancery Court granted the parties’ stipulation to set a briefing schedule regarding defendants’ response to the complaint. Pursuant to that order, defendants shall serve an answer or motion to dismiss the complaint by January 20, 2014. If defendants move to dismiss the complaint, then plaintiffs must file and serve an opposition brief by February 17, 2014, and defendants must file and serve their reply by March 3, 2014.

*Other Legal Matters*

On September 24, 2012, we filed a lawsuit, captioned *Peregrine Pharmaceuticals, Inc. v. Clinical Supplies Management, Inc.*, Case No. 8:12-cv-01608 JST(AN) (C.D. Cal), against Clinical Supplies Management, Inc. (“CSM”), in the U.S. District Court for the Central District of California. In 2010, we had contracted with CSM as our third-party vendor responsible for distribution of the blinded investigational product used in our bavituximab Phase IIb second-line NSCLC trial. As part of the routine collection of data in advance of an end-of-Phase II meeting with regulatory authorities, we discovered major discrepancies between some patient sample test results and patient treatment code assignments. Consequently, we filed this lawsuit against CSM alleging breach of contract, negligence and negligence per se arising from CSM’s performance of its contracted services. We are seeking monetary damages. On March 7, 2013, we and CSM submitted to the court a proposed stipulation pursuant to which the lawsuit would be stayed for up to 120 days during which time we and CSM would participate in an alternative dispute resolution process, pursuant to our contract with CSM. The proposed stipulation was approved by the court on March 8, 2013. On June 26, 2013, we and CSM engaged in an alternative dispute resolution session that did not result in any resolution of our dispute. The aforementioned stay expired on July 6, 2013. We granted CSM until July 19, 2013 to file an answer to our complaint, which CSM did on July 11, 2013. No further activity has occurred since that date.



## ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which represent our projections, estimates, expectations or beliefs concerning among other things, financial items that relate to management’s future plans or objectives or to our future economic and financial performance. In some cases, you can identify these statements by terminology such as “may”, “should”, “plans”, “believe”, “will”, “anticipate”, “estimate”, “expect” “project”, or “intend”, including their opposites or similar phrases or expressions. You should be aware that these statements are projections or estimates as to future events and are subject to a number of factors that may tend to influence the accuracy of the statements. These forward-looking statements should not be regarded as a representation by the Company or any other person that the events or plans of the Company will be achieved. You should not unduly rely on these forward-looking statements, which speak only as of the date of this Quarterly Report. We undertake no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this Quarterly Report or to reflect the occurrence of unanticipated events. You should, however, review the factors and risks we describe in the reports we file from time to time with the Securities and Exchange Commission (“SEC”) after the date of this Quarterly Report. Actual results may differ materially from any forward looking statement.

### Overview

We are a biopharmaceutical company with a portfolio of innovative monoclonal antibodies in clinical trials focused on the treatment and diagnosis of cancer. We are advancing our lead immunotherapy candidate, bavituximab, into Phase III development for the treatment of second-line non-small cell lung cancer (the “SUNRISE trial”) while also seeking a licensing or funding partner to further advance Cotara into Phase III development for the treatment of brain cancer. In addition, we are evaluating our lead molecular imaging agent, 124I-PGN650, in an exploratory clinical trial for the imaging of multiple solid tumor types.

Our pipeline of novel investigational monoclonal antibodies is based on two first-in-class technology platforms, including phosphatidylserine (“PS”)-targeting antibodies and DNA/histone-targeting antibody (Cotara). The following represents a summary of our clinical trials and current status under these first-in-class technology platforms with respect to our oncology and imaging programs in clinical-stage development. Additional information pertaining to each clinical trial is further discussed below.

Product Candidate	Trial	Phase	Status
Bavituximab PS-Targeting Monoclonal Antibody (oncology)	Non-small cell lung cancer (“NSCLC”), second-line, randomized, double blind, placebo-controlled, combined with docetaxel (lead indication) called the SUNRISE trial (Stimulating ImmUne RespoNse thRough BavItuximab in a PhaSE III Lung Cancer Study)	III	Trial expected to be initiated by December 31, 2013.
	NSCLC, second-line, randomized, double-blind, placebo-controlled, combined with docetaxel	Ib	Completed; Final data announced in June 2013 as further described below.
	Pancreatic, front-line, randomized, open-label, combined with gemcitabine	II	Completed; Final data announced in June 2013 as further described below.
	NSCLC, front-line, randomized, open-label, combined with carboplatin and paclitaxel	II	Completed; Data announced in June 2013 as further described below.
	NSCLC, front-line, randomized, open-label, combined with carboplatin and pemetrexed	Ib	Patient enrollment ongoing; Interim data described below.
	HER2-negative breast cancer (MBC), randomized, open-label, combined with paclitaxel	I	Patient enrollment complete; Interim data announced in June 2013 as further described below.
	Liver (HCC), front-line, non-randomized, open-label, combined with sorafenib	I/II	Patient enrollment ongoing; Phase I portion of trial enrolled. Phase II portion of trial enrolling. Interim safety data described below.
	Rectal adenocarcinoma, front-line, randomized, open-label, combined with capecitabine and radiation	I	Patient enrollment ongoing; No data reported to date.

Product Candidate	Trial	Phase	Status
<b>PGN650</b> PS-targeting F(ab') <sub>2</sub> fully human monoclonal antibody (imaging)	Imaging agent	I*	Patient enrollment ongoing; No data reported to date.
<b>Cotara</b> DNA/histone-targeting monoclonal antibody (oncology)	Glioblastoma multiforme (GBM) (brain cancer)	II	Completed; Reached agreement with FDA on Phase III trial design; Seeking partner to advance to Phase III.

\* Filed under an exploratory Investigational New Drug Application ("IND").

## Bavituximab for the Treatment of Solid Tumors

We believe our novel immunotherapy candidate bavituximab may have broad potential for the treatment of multiple types of cancer. We have conducted three randomized Phase II trials for bavituximab in combination with standard chemotherapy in front and second-line NSCLC and front-line pancreatic cancer. In addition, we have four ongoing investigator-sponsored trials evaluating different treatment combinations and additional oncology indications for bavituximab.

The following represents an overview of our bavituximab clinical trials:

### Bavituximab in Second-Line NSCLC

#### *Phase III SUNRISE Trial – Bavituximab Plus Docetaxel in Second-Line NSCLC*

In May 2013, we reached an agreement with the U.S. Food and Drug Administration ("FDA") on a Phase III registration trial design of our lead clinical immunotherapeutic candidate bavituximab in second-line NSCLC called the SUNRISE trial (Stimulating ImmUne RespoNse thRough BavItuximab in a PhaSE III Lung Cancer Study). The SUNRISE trial design was supported by promising data from our Phase IIb second-line NSCLC trial in the same indication which is described under the heading "*Phase IIb Trial – Bavituximab Plus Docetaxel in Second-Line NSCLC*" below.

The Phase III SUNRISE trial is a randomized, double-blind, placebo-controlled trial evaluating bavituximab plus docetaxel versus docetaxel alone in approximately 600 patients at clinical sites worldwide. The trial will enroll non-squamous, NSCLC patients who have progressed after standard front-line treatment. Patients will be randomized into one of two treatment arms. One treatment arm will receive docetaxel (75 mg/m<sup>2</sup>), up to six 21-day cycles, in combination with bavituximab (3 mg/kg) weekly until progression or toxicity. The other treatment arm will receive docetaxel (75 mg/m<sup>2</sup>), up to six 21-day cycles, in combination with placebo weekly until progression or toxicity. The primary endpoint of the trial will be overall survival. We anticipate initiating this trial by December 31, 2013.

#### *Phase IIb Trial – Bavituximab Plus Docetaxel in Second-Line NSCLC*

We conducted a randomized, double-blind, placebo-controlled Phase IIb second-line NSCLC trial evaluating two dose levels of bavituximab plus docetaxel ("bavituximab-containing arms") versus docetaxel plus placebo ("control arm") as second-line treatment in 121 patients with Stage IIIb/IV NSCLC. Patients were randomized to one of three treatment arms at clinical sites worldwide and enrollment was completed in October 2011. All patients were randomized to receive up to six 21-day cycles of docetaxel (75 mg/m<sup>2</sup>). In addition, one arm was randomized to receive bavituximab (3 mg/kg) weekly, a second arm was randomized to receive bavituximab (1 mg/kg) weekly, and a third arm was randomized to receive placebo weekly until progression or toxicity. The trial was designed to evaluate overall response rate ("ORR"), the primary endpoint, measured in accordance with Response Evaluation Criteria In Solid Tumors ("RECIST") criteria, and progression-free survival ("PFS"), duration of response, overall survival ("OS"), and safety, were secondary endpoints.

On September 24, 2012, we announced that during the course of preparing for an end-of-Phase II meeting with regulatory authorities and following the data announcement on September 7, 2012 from this Phase IIb trial, we discovered major discrepancies between some patient sample test results and patient treatment code assignments. As a result of these discrepancies, the data that we disclosed on or before September 7, 2012 should not be relied upon.

Upon discovery of the discrepancies, we initiated an internal review of this Phase IIb trial, which included the testing of investigational product, patient samples, reviewing the operations of multiple vendors, among other activities. The initial results of this internal review were announced on January 7, 2013, and indicated that discrepancies were isolated to the control and 1 mg/kg bavituximab-containing treatment arms of the trial and that there was no evidence of discrepancies in the 3 mg/kg bavituximab-containing treatment arm of the trial. Based on the results of our internal review, we took a conservative approach toward analyzing the results from the trial, which included combining the control arm and 1 mg/kg bavituximab-containing arm into one treatment arm (“combined control arm”), and comparing those results to the 3 mg/kg bavituximab-containing treatment arm.

On February 19, 2013, we reported updated top-line survival data from this trial based upon the completion of the aforementioned internal review of discrepancies in the trial and updated patient survival data from the trial. Updated top-line data from this Phase IIb trial indicate a meaningful improvement in median OS of 11.7 months in the 3 mg/kg bavituximab-containing arm compared to 7.3 months in the combined control arm.

On June 3, 2013, we presented the following final data from this Phase IIb trial at the 2013 American Society of Clinical Oncology Annual Meeting:

	<b>3 mg/kg Bavituximab Containing Arm</b>	<b>Combined Control Arm</b>
Median Overall Survival	11.7 months	7.3 months
Overall Response Rate	17.1%	11.3%
Median Progression-Free Survival	4.2 months	3.9 months

In addition, subgroup analyses of overall survival by key patient characteristics favored the bavituximab 3 mg/kg containing arm, including age, gender, Eastern Cooperative Oncology Group (“ECOG”) status, ethnicity and prior treatment. The results also indicated that the 3 mg/kg bavituximab plus docetaxel combination was well-tolerated with no significant differences in adverse events between the two trial arms.

Based on these data and discussions with our medical advisors, we are advancing bavituximab into Phase III development as further discussed above.

### **Bavituximab in Front-Line NSCLC**

#### ***Phase II Trial – Bavituximab Plus Paclitaxel/Carboplatin in Front-Line NSCLC***

Our Phase II trial was designed to assess bavituximab in combination with paclitaxel and carboplatin in front-line NSCLC. This randomized trial enrolled 86 patients (enrollment completed in September 2011) at clinical sites worldwide. Patients were randomized to one of two treatment arms. All patients were randomized to receive up to six 21-day cycles of paclitaxel and carboplatin (“C/P”). In addition, one arm was randomized to receive bavituximab (3 mg/kg) weekly until progression or toxicity. The primary endpoint of this trial is ORR and secondary endpoints include median PFS, median OS, duration of response, and safety. Patients were evaluated regularly for tumor response according to RECIST criteria.

In March 2012, we announced top-line data from this Phase II trial in which the primary ORR endpoint was determined. Initial ORR and median PFS data from this trial were deemed inconclusive and therefore, it was determined that median OS, another secondary endpoint, would be an important data point in determining our next steps in advancing bavituximab in front-line NSCLC in combination with carboplatin and paclitaxel.

Prompted by the enhanced understanding of bavituximab's immunotherapy mechanism of action that we presented at the 2013 American Academy for Cancer Research (“AACR”) Annual Meeting, we undertook a review of our entire ongoing bavituximab clinical program, including an early analysis of this Phase II front-line NSCLC trial, in order to better direct our clinical development strategy. Results from this analysis, which included less than 60% of survival events, were announced in June 2013 and indicated that, while the bavituximab containing treatment arm currently demonstrated a median OS of over 14 months, there was no meaningful difference in survival between the two arms of the trial that would support the advancement of this combination and the current timing of therapy. Separately, an independent trial with another immunotherapy agent showed that when C/P are given together with immunotherapy, as was done in this trial, the results were similar to the control arm while starting with C/P before administering the immunotherapy gave much more favorable results. This trial is complete and we are evaluating options for moving bavituximab forward in front-line NSCLC.

### ***Phase Ib Trial – Bavituximab Plus Pemetrexed/Carboplatin in Front-Line NSCLC***

This investigator-sponsored Phase Ib trial is designed to assess bavituximab with pemetrexed and carboplatin in up to 25 patients with locally advanced or metastatic NSCLC. Interim data conducted on a small number of patients showed encouraging response rates with the combination of carboplatin, pemetrexed and bavituximab. This trial continues to enroll and dose patients.

### ***Bavituximab in Pancreatic Cancer***

Our Phase II trial was designed to assess bavituximab in combination with gemcitabine in previously untreated Stage IV pancreatic cancer patients. This randomized trial enrolled 70 patients (enrollment completed in June 2012) at clinical sites worldwide. Patients were randomized to one of two treatment arms. All patients were randomized to receive gemcitabine (1000 mg/m<sup>2</sup>) on days 1, 8 and 15 of each 28-day cycle (4 weeks) until disease progression or unacceptable toxicities. In addition, patients in one arm were randomized to receive bavituximab (3 mg/kg) weekly. The primary endpoint of this trial was median OS and secondary endpoints included median PFS, ORR, duration of response, and safety. Patients were evaluated regularly for tumor response according to RECIST criteria.

In February 2013, we announced results from this trial showing that the combination of bavituximab and gemcitabine resulted in more than a doubling of ORR and an improvement in OS when compared with gemcitabine alone (control arm). In the trial, patients treated with a combination of bavituximab and gemcitabine had a 28% tumor response rate as compared to 13% in the control arm. Median OS was 5.6 months for the bavituximab plus gemcitabine arm and 5.2 months for the control arm. In this trial, bavituximab was generally safe and well tolerated in combination with gemcitabine with similar adverse events occurring in both arms. As this trial allowed for the enrollment of patients 18 and older without any age limit, distant organ involvement and ECOG performance status of 0-2, further analysis of the patient group was warranted.

In June 2013, we announced final results from this trial which included a further analysis of patient subgroups. Median OS, PFS and ORR results were unchanged from the February 2013 announcement with data showing encouraging activity in this patient population with very rapid disease progression.

Results from a subgroup analysis showed that the effect of bavituximab plus gemcitabine was more pronounced in patients with ECOG  $\leq$  1 and those without hepatic metastases. While we believe the final data combined with the results from subgroup analyses warrant future consideration, given the fast progression of pancreatic cancer and the need for longer treatment periods associated with immunotherapies such as bavituximab, there are no plans to initiate a follow-on trial in pancreatic cancer at this time.

### ***Bavituximab in HER2-negative Metastatic Breast Cancer (MBC)***

This ongoing investigator-sponsored Phase I trial is designed to assess bavituximab combined with paclitaxel in up to 14 patients with HER2-negative metastatic breast cancer. In June 2013, investigators reported interim results from 13 evaluable patients showing that 85% of patients achieved an objective tumor response, including 15% of patients achieving a complete response measured in accordance with RECIST criteria. All patients have been enrolled in the trial.

### ***Bavituximab in Advanced Liver Cancer***

This ongoing investigator-sponsored Phase I/II trial is designed to assess bavituximab combined with sorafenib (Nexavar<sup>®</sup>) in up to 48 patients with advanced liver cancer (hepatocellular carcinoma, or HCC). Data presented at AACR in April 2012 showed that of the nine patients enrolled in the Phase I portion of the study, no dose-limiting toxicities or serious adverse events were observed and the trial is now enrolling in the Phase II part of the study. This trial continues to enroll and dose patients.

### ***Bavituximab in Rectal Adenocarcinoma***

This ongoing investigator-sponsored Phase I trial is designed to assess bavituximab in combination with capecitabine and radiation therapy in up to 18 patients with Stage II or III rectal adenocarcinoma. The primary endpoint is to determine the safety, feasibility and tolerability with a standard platform of capecitabine and radiation therapy. Secondary endpoints include ORR and histopathological response in patients. This trial continues to enroll and dose patients.

## **PS-Targeting Molecular Imaging Program (PGN650)**

In addition to our PS-targeting antibodies potential to treat cancer, we believe these antibodies may have broad potential for the imaging and diagnosis of multiple diseases, including cancer. PS-targeting antibodies are able to target diseases that present PS on the surface of distressed cells, which we believe is present in multiple disease settings. In oncology, PS is a molecule usually located inside the membrane of healthy cells, but "flips" and becomes exposed on the outside of cells that line tumor blood vessels, creating a specific target for the imaging of multiple solid tumor types.

Our initial clinical candidate is PGN650, a first-in-class PS-targeting F(ab')<sub>2</sub> fully human monoclonal antibody fragment joined to the positron emission tomography ("PET") imaging radio-isotope iodine-124 (<sup>124</sup>I) that represents a potential new approach to imaging cancer. In preclinical studies, PGN650 accumulates in tumor vasculature and provides exceedingly clear in vivo tumor images.

The initial goal for the PGN650 program is to further validate the broad nature of the PS-targeting platform in the clinic. Our current PGN650 clinical trial evaluating PGN650 imaging in multiple solid tumor types in up to 12 patients was filed under an exploratory IND with the FDA. The primary goal of the trial is to estimate radiation dosimetry in critical and non-critical organs and secondary trial objectives include tumor imaging and safety. Results from this study may open the door for multiple applications including development of antibody drug conjugates, the ability of PGN650 to monitor the effectiveness of current standard cancer treatments, and the ability to potentially select patients that may benefit from baviximab-based treatment. Patients will receive an imaging dose followed by three (3) PET images: two images on day one and one image on either day two or three. Successful results from this trial could support several promising new areas of research in the imaging and diagnostic fields. This trial continues to enroll and dose patients.

## **Cotara for the Treatment of Brain Cancer**

Cotara is our lead DNA/histone-targeting antibody and represents a novel approach to treating brain cancer. Cotara is a monoclonal antibody linked to a radioisotope (Iodine 131) that is administered as a single-infusion, one-time therapy directly into the tumor, thereby destroying the tumor from the inside out with minimal exposure to surrounding healthy tissue. In four prior clinical studies, Cotara has demonstrated encouraging survival, localization to the tumor, and an acceptable safety profile in patients with brain cancer.

Cotara has been granted FDA and European Medicines Agency ("EMA") orphan drug status for GBM and anaplastic astrocytoma and fast track designation in the U.S. for the treatment of recurrent GBM.

In our Phase II single-arm, multicenter trial, 41 patients with GBM at first relapse received a single Cotara treatment. The primary endpoint was safety and tolerability of the maximum tolerated dose, a single 25-hour interstitial infusion of 2.5 mCi/cc of Cotara. Secondary endpoints include median OS, median PFS, and proportion of patients alive at six months after treatment. Median OS for patients treated with Cotara was 9.3 months, consistent with a prior Phase II trial.

Cotara was generally safe and well tolerated in this trial. The most common drug-related adverse events (AEs) were neurologic in nature and most were managed with corticosteroids.

In December 2012, we reached an agreement with the FDA on the design of a single randomized registration trial comparing two dose levels of Cotara in up to 300 patients. We are currently seeking a partner to further develop Cotara in recurrent GBM.

## Results of Operations

The following table compares the interim unaudited condensed consolidated statements of operations for the three and six-month periods ended October 31, 2013 and 2012. This table provides you with an overview of the changes in the condensed consolidated statements of operations for the comparative periods, which are further discussed below.

	Three Months Ended October 31,			Six Months Ended October 31,		
	2013	2012	\$ Change	2013	2012	\$ Change
<b>REVENUES:</b>						
Contract manufacturing revenue	\$ 7,354,000	\$ 6,061,000	\$ 1,293,000	\$ 11,935,000	\$ 10,196,000	\$ 1,739,000
License revenue	–	78,000	(78,000)	107,000	194,000	(87,000)
Total revenues	7,354,000	6,139,000	1,215,000	12,042,000	10,390,000	1,652,000
<b>COSTS AND EXPENSES:</b>						
Cost of contract manufacturing	4,195,000	3,703,000	492,000	6,865,000	5,727,000	1,138,000
Research and development	6,957,000	6,053,000	904,000	12,261,000	13,034,000	(773,000)
Selling, general & administrative	4,016,000	3,440,000	576,000	8,350,000	6,357,000	1,993,000
Total costs and expenses	15,168,000	13,196,000	1,972,000	27,476,000	25,118,000	2,358,000
<b>LOSS FROM OPERATIONS</b>	<b>(7,814,000)</b>	<b>(7,057,000)</b>	<b>(757,000)</b>	<b>(15,434,000)</b>	<b>(14,728,000)</b>	<b>(706,000)</b>
<b>OTHER INCOME (EXPENSE):</b>						
Interest and other income	24,000	44,000	(20,000)	45,000	52,000	(7,000)
Interest and other expense	–	(44,000)	44,000	(1,000)	(45,000)	44,000
Loss on the early extinguishment of debt	–	(1,696,000)	1,696,000	–	(1,696,000)	1,696,000
<b>NET LOSS</b>	<b>\$ (7,790,000)</b>	<b>\$ (8,753,000)</b>	<b>\$ 963,000</b>	<b>\$ (15,390,000)</b>	<b>\$ (16,417,000)</b>	<b>\$ 1,027,000</b>

Results of operations for interim periods covered by this Quarterly Report on Form 10-Q may not necessarily be indicative of results of operations for the full fiscal year.

### **Total Revenues**

Three Months: The increase in total revenues of \$1,215,000 (20%) during the three months ended October 31, 2013 compared to the same period in the prior year was due to an increase in contract manufacturing revenue of \$1,293,000 offset by a \$78,000 decrease in license revenue. The increase in contract manufacturing revenue was primarily associated with additional process development related services provided in the current period compared to the same prior year period.

Six Months: The increase in total revenues of \$1,652,000 (16%) during the six months ended October 31, 2013 compared to the same period in the prior year was due to an increase in contract manufacturing revenue of \$1,739,000 offset by an \$87,000 decrease in license revenue. The increase in contract manufacturing revenue was primarily due to an increase in the number of manufacturing runs completed in the current year six-month period compared to the same prior year period combined with an increase in process development related services due to an increase in demand for services.

Based on the current commitments for manufacturing services from Avid's third-party customers and the anticipated completion of in-process third-party customer manufacturing runs, we expect contract manufacturing revenue for fiscal year 2014 to be in-line with total revenues reported in fiscal year 2013. In addition, based on our existing license agreements, we do not expect to recognize additional license revenue for the remainder of the current fiscal year.

### Cost of Contract Manufacturing

Three and Six Months: The increases cost of contract manufacturing of \$492,000 (13%) and \$1,138,000 (20%) during the three and six months ended October 31, 2013, respectively, compared to the same periods in the prior year was primarily due to the current year three and six-month period increases in contract manufacturing revenue. In addition, due to the similar mix of services completed during the current and prior year periods, our current year three and six-month period gross margins of 43% and 42%, respectively, remained in-line with our prior year three and six-month gross margins of 39% and 44%, respectively.

### Research and Development Expenses

Research and development (“R&D”) expenses primarily include (i) payroll and related costs associated with research and development personnel, (ii) share-based compensation expense associated with share-based awards granted to research and development personnel (iii) costs related to clinical and preclinical testing of our technologies under development, (iv) costs to develop and manufacture the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses, (v) expenses for research services provided by universities and contract laboratories, including sponsored research funding, and (vi) other research and development expenses.

Three Months: The increase in R&D expenses of \$904,000 (15%) during the three months ended October 31, 2013 compared to the same period in the prior year was due to the following changes associated with each of our following technology platforms under development:

<i>Technology Platform</i>	<i>R&amp;D Expenses - Three Months Ended October 31, 2013</i>	<i>R&amp;D Expenses - Three Months Ended October 31, 2012</i>	<i>\$ Change</i>
PS-Targeting	\$ 6,571,000	\$ 5,820,000	\$ 751,000
Cotara <sup>®</sup>	386,000	233,000	153,000
Total R&D Expenses	<u>\$ 6,957,000</u>	<u>\$ 6,053,000</u>	<u>\$ 904,000</u>

- o *PS-Targeting (bavituximab and PGN650)* – The increase in PS-targeting program expenses of \$751,000 during the three months ended October 31, 2013 compared to the same period in the prior year was primarily due to increases in third-party vendor costs and manufacturing expenses associated with preparing for the initiation of our Phase III SUNRISE trial combined with an increase in share-based compensation expense. These current year three-month period increases in PS-targeting program expenses were offset by decreases in third-party vendor costs regarding our three separate company-sponsored Phase II trials using bavituximab in combination with chemotherapy for the treatment of patients with (i) front-line NSCLC, (ii) second-line NSCLC, and (iii) pancreatic cancer, as patient enrollment in these trials was completed in the prior fiscal year.
- o *Cotara* – The increase in Cotara related expenses of \$153,000 during the three months ended October 31, 2013 compared to the same period in the prior year was primarily due to incremental increases in manufacturing costs, payroll and related expenses and share-based compensation expense.

Six Months: The decrease in R&D expenses of \$773,000 (6%) during the six months ended October 31, 2013 compared to the same period in the prior year was due to the following changes associated with each of our following technology platforms under development:

<i>Technology Platform</i>	<i>R&amp;D Expenses - Six Months Ended October 31, 2013</i>	<i>R&amp;D Expenses - Six Months Ended October 31, 2012</i>	<i>\$ Change</i>
PS-Targeting	\$ 10,560,000	\$ 12,521,000	\$ (1,961,000)
Cotara <sup>®</sup>	1,701,000	513,000	1,188,000
Total R&D Expenses	<u>\$ 12,261,000</u>	<u>\$ 13,034,000</u>	<u>\$ (773,000)</u>

- o *PS-Targeting (bavituximab and PGN650)* – The decrease in PS-targeting program expenses of \$1,961,000 during the six months ended October 31, 2013 compared to the same period in the prior year was primarily due to decreases in third-party vendor costs regarding our three separate company-sponsored Phase II trials using bavituximab in combination with chemotherapy for the treatment of patients with (i) front-line NSCLC, (ii) second-line NSCLC, and (iii) pancreatic cancer, as patient enrollment in these trials was completed in the prior fiscal year. These decreases in clinical trial expenses were further supplemented with a decrease in manufacturing costs incurred in the current year period due to timing of needed manufacturing services combined with a decrease in technology license fees associated with our PS-targeting program. These current year six-month period decreases in PS-targeting program expenses were offset by increases in third-party vendor costs associated with preparing for the initiation of our Phase III SUNRISE trial and share-based compensation expense.
- o *Cotara* – The increase in Cotara related expenses of \$1,188,000 during the six months ended October 31, 2013 compared to the same period in the prior year was primarily due to an increase in manufacturing costs associated with preparing Cotara for potential later-stage clinical trials for the treatment of GBM combined with an increase in share-based compensation expense.

Based on our current projections, we expect research and development expenses in fiscal year 2014 to increase in comparison to fiscal year 2013 as we advance our Phase III SUNRISE trial and continue our exploration of bavituximab's broad potential in the treatment and diagnosis of cancer in other indications and combinations. These projections include a number of uncertainties, including but not limited to, (i) the uncertainty of the rate at which patients will be enrolled in any current or future clinical trials, including, our Phase III SUNRISE trial, (ii) the uncertainty of future clinical and preclinical studies, which are dependent upon the results of current clinical and preclinical studies, (iii) the uncertainty of obtaining regulatory approval to advance our current exploratory IND clinical program to Phase I or to commence any future trials, and (iv) the uncertainty of terms related to any potential future partnering or licensing arrangement. During fiscal year 2014, we expect to continue to direct the majority of our research and development expenses towards our PS-targeting technology platform as we are actively seeking potential partners to further advance the Cotara clinical program.

Looking beyond fiscal year 2014, we expect to continue to direct the majority of our research and development expenses towards our PS-targeting technology platform although it is extremely difficult for us to reasonably estimate all future research and development costs associated with each of our technologies due to the number of unknowns and uncertainties associated with preclinical and clinical trial development. These unknown variables and uncertainties include, but are not limited to:

- the uncertainty of the progress and results of our ongoing preclinical and clinical studies, and any additional preclinical and clinical studies we may initiate in the future based on their results;
- the uncertainty of the ultimate number of patients to be treated in any current or future clinical study;
- the uncertainty of the FDA allowing our non-lead indication oncology studies to move forward from Phase I clinical studies to Phase II clinical studies or Phase II clinical studies to Phase III clinical studies;
- the uncertainty of the FDA allowing our lead molecular imaging agent, PGN650, to move forward from an exploratory study to a Phase I or Phase II clinical study;
- the uncertainty of the rate at which patients are enrolled into any current or future study. Any delays in clinical trials could significantly increase the cost of the study and would extend the estimated completion dates;
- the uncertainty of terms related to potential future partnering or licensing arrangements;
- the uncertainty of protocol changes and modifications in the design of our clinical trial studies, which may increase or decrease our future costs; and
- the uncertainty of our ability to raise additional capital to support our future research and development efforts beyond September 2014.

We or our potential partners will need to do additional development and clinical testing prior to seeking any regulatory approval for commercialization of our product candidates as all of our products are in discovery, preclinical or clinical development. Testing, manufacturing, commercialization, advertising, promotion, exporting, and marketing, among other things, of our proposed products are subject to extensive regulation by governmental authorities in the United States and other countries. The testing and approval process requires substantial time, effort, and financial resources, and we cannot guarantee that any approval will be granted on a timely basis, if at all. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in conducting advanced human clinical trials, even after obtaining promising results in earlier trials. Furthermore, the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Even if regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which it may be marketed. Accordingly, we or our potential partners may experience difficulties and delays in obtaining necessary governmental clearances and approvals to market our products.



### ***Selling, General and Administrative Expenses***

Selling, general and administrative (“SG&A”) expenses consist primarily of payroll and related expenses, director fees, share-based compensation expense, legal fees, audit and accounting fees, patent fees, investor and public relation fees, insurance, and other expenses relating to the general management, administration, and business development activities of the Company.

Three Months: The increase in SG&A expenses of \$576,000 (17%) during the three months ended October 31, 2013 compared to the same period in the prior year was primarily due to increases in share-based compensation expense and payroll and related expenses of \$653,000 and \$300,000, respectively. These amounts were offset by an aggregate current period decrease of \$395,000 associated with decreases in corporate legal fees, market research fees, audit and accounting fees, and annual shareholder meeting expenses. The increase in share-based compensation expense (non-cash) was primarily related to the amortization of the fair value of options granted to employees and board members under a non-routine broad based grant during December 2012 and a routine annual broad-based grant during May 2013. The increase in payroll and related expenses was primarily attributed to increases in compensation and other employee-related benefits.

Six Months: The increase in SG&A expenses of \$1,993,000 (31%) during the six months ended October 31, 2013 compared to the same period in the prior year was primarily due to increases in share-based compensation expense and payroll and related expenses of \$1,150,000 and \$672,000, respectively. The increase in share-based compensation expense (non-cash) was primarily related to the amortization of the fair value of options granted to employees and board members under a non-routine broad based grant during December 2012 and a routine annual broad-based grant during May 2013. The increase in payroll and related expenses was primarily attributed to increases in compensation and other employee-related benefits.

### ***Loss on Early Extinguishment of Debt***

Three and Six Months: The decreases in loss on early extinguishment of debt of \$1,696,000 during the three and six months ended October 31, 2013, respectively, compared to the same periods in the prior year were directly related to the term loan we entered into during the quarter ended October 31, 2012 that was subsequently repaid in full and terminated in the same quarter under an event of default (as described in Note 6 to the accompanying interim unaudited condensed consolidated financial statements). Upon the termination of the term loan, we recorded a loss on the early extinguishment of debt of \$1,696,000, which consisted of a final payment fee of \$975,000, the unamortized debt discount associated with the fair value of the warrants issued to the lenders under the term loan of \$470,000, and unamortized aggregate debt issuance costs of \$251,000. The loss on the early extinguishment of debt is included in the accompanying interim unaudited condensed consolidated statements of operations and comprehensive loss for the three and six months ended October 31, 2012.

### **Critical Accounting Policies and Estimates**

Our discussion and analysis of our consolidated financial position and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures. We review our estimates and assumptions on an ongoing basis. We base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could change our reported results. During the three and six months ended October 31, 2013, there were no significant changes in our critical accounting policies as previously disclosed by us in Part II, Item 7 of our Annual Report for the fiscal year ended April 30, 2013.

### **Liquidity and Capital Resources**

At October 31, 2013, we had \$44,443,000 in cash and cash equivalents. We have expended substantial funds on the research and development of our product candidates, and funding the operations of Avid. As a result, we have historically experienced negative cash flows from operations since our inception and we expect negative cash flows from operations to continue in the foreseeable future. Our net loss incurred during the six-month period ended October 31, 2013 amounted to \$15,390,000 and our net losses incurred during the past three fiscal years ended April 30, 2013, 2012 and 2011, amounted to \$29,780,000, \$42,119,000, and \$34,151,000, respectively. Therefore, unless and until we are able to generate sufficient revenues from Avid’s contract manufacturing services and/or from the sale and/or licensing of our products under development, we expect such losses to continue in the foreseeable future.

Therefore, our ability to continue to fund our clinical trials and development efforts is highly dependent on the amount of cash and cash equivalents on hand combined with our ability to raise additional capital to support our future operations through one or more methods, including but not limited to, issuing additional equity or debt.

Historically, we have funded a significant portion of our operations through the issuance of equity. During the six months ended October 31, 2013, we raised \$24,277,000 in aggregate gross proceeds under an At Market Sales Issuance Agreement (as described in Note 7 to the accompanying interim unaudited condensed consolidated financial statements). With these proceeds, we currently estimate that we have sufficient cash resources to meet our anticipated cash needs to fund our operations through at least September 2014 based on our current projections, which includes projected costs associated with our pivotal Phase III SUNRISE trial, projected cash inflows under signed contracts with existing customers of Avid and assuming we raise no additional capital from the capital markets or other potential sources.

However, our ability to continue to fund our clinical trials and development efforts in future years, including costs to fund our pivotal Phase III SUNRISE trial beyond September 2014, is highly dependent on our ability to raise additional capital to support our future operations through one or more methods, including but not limited to, financing our operations through the issuance of equity, securing new funding through the issuance of debt, licensing or partnering our products in development, or increasing revenue from our wholly-owned subsidiary, Avid. While we will continue to explore these potential opportunities, we may not be successful in securing debt financing, licensing or partnering our products in development, or generating additional revenue from Avid to complete the research, development, and clinical testing of our product candidates. Even if we are successful in obtaining debt financing, it may involve restrictive covenants on the operation of our business and require significant interest payments.

With respect to our ability to raise additional capital from the issuance of equity, as of October 31, 2013, we have an effective shelf registration statement on Form S-3, under which we may issue, from time to time, in one or more offerings, shares of our common stock for gross proceeds of up to \$112,351,000. However, our ability to raise additional capital in the equity markets is dependent on a number of factors, including, but not limited to, the market demand for our common stock. The market demand or liquidity of our common stock is subject to a number of risks and uncertainties, including but not limited to, negative economic conditions, adverse market conditions, adverse clinical trial results and significant delays in one or more clinical trials. If our ability to access the capital markets becomes severely restricted, it could have a negative impact on our business plans, including our clinical trial programs and other research and development activities. In addition, even if we are able to raise additional capital, it may not be at a price or on terms that are favorable to us.

Significant components of the changes in cash flows from operating, investing, and financing activities for the six months ended October 31, 2013 compared to the same prior year period are as follows:

*Cash Used In Operating Activities.* Net cash used in operating activities represents our (i) net loss, as reported, (ii) less non-cash operating expenses, and (iii) net changes in the timing of cash flows as reflected by the changes in operating assets and liabilities, as described in the below table:

	<b>Six Months Ended October 31,</b>	
	<b>2013</b>	<b>2012</b>
Net loss, as reported	\$ (15,390,000)	\$ (16,417,000)
Less non-cash operating expenses:		
Share-based compensation	3,313,000	1,291,000
Depreciation and amortization	493,000	526,000
Loss on early extinguishment of debt	–	1,696,000
Net cash used in operating activities before changes in operating assets and liabilities	\$ (11,584,000)	\$ (12,904,000)
Net change in operating assets and liabilities	\$ (2,026,000)	\$ 3,246,000
Net cash used in operating activities	\$ (13,610,000)	\$ (9,658,000)

Net cash used in operating activities for the six months ended October 31, 2013 was \$13,610,000 compared to \$9,658,000 for the same period in the prior year, representing an increase of \$3,952,000. This increase in net cash used in operating activities was due to a net change in operating assets and liabilities of \$5,272,000 offset by a decrease of \$1,320,000 in net loss reported during the current six-month period after deducting non-cash operating expenses. The net change in operating assets and liabilities was primarily due to decreases in customer deposits and deferred revenue associated with payments received in the prior year period from Avid's third-party customers offset by a decrease in inventories. The decrease in our current six-month net loss was primarily due to a current period increase in total revenues combined with decreases in research and development expenses and loss on early extinguishment of debt, offset by increases in cost of contract manufacturing and selling, general and administrative expenses.

*Cash Used In Investing Activities.* Net cash used in investing activities increased \$583,000 to \$1,093,000 for the six months ended October 31, 2013 compared to net cash used in investing activities of \$510,000 for the six months ended October 31, 2012. This net increase was due to an increase in other assets of \$839,000 offset by a decrease in property and equipment acquisitions of \$256,000. The current period increase in other assets was primarily related to current year deposits and/or progress payments for certain additional computer software to enhance operating efficiencies combined with certain additional laboratory equipment to support internal product development efforts and business opportunities at Avid. The current period decrease in property and equipment acquisitions was primarily related to a decrease in laboratory equipment, office equipment and software purchases compared to the prior year period.

*Cash Provided By Financing Activities.* Net cash provided by financing activities increased \$7,364,000 to \$23,942,000 for the six months ended October 31, 2013 compared to net cash provided by financing activities of \$16,578,000 for the six months ended October 31, 2012. Net cash provided by financing activities for the six months ended October 31, 2013 consisted of \$23,555,000 in net proceeds raised from the sale of shares of our common stock under an At Market Issuance Sales Agreement combined with \$411,000 in aggregate net proceeds received from the purchase of shares under our Employee Stock Purchase plan and from stock option exercises, which were offset by principal payments on capital leases of \$24,000. Net cash provided by financing activities for the six months ended October 31, 2012, consisted of \$17,595,000 in net proceeds raised from the sale of shares of our common stock under an At Market Issuance Sales Agreement combined with \$248,000 in aggregate net proceeds received from the purchase of shares under our Employee Stock Purchase plan and from stock option exercises, which were offset by principal payments on capital leases of \$39,000. In addition, during the prior year six-month period, we received gross proceeds of \$15,000,000 under a term loan, excluding debt issuance costs of \$251,000, which principal amount was repaid in full during the prior year six-month period upon the termination of the term loan agreement on September 25, 2012 (as described in Note 6 to the accompanying interim unaudited condensed consolidated financial statements). In addition, we paid a final payment fee of \$975,000 upon the termination of the term loan.

#### **Commitments**

At October 31, 2013, we had remaining capital commitments in the amount of \$351,000 to purchase certain laboratory equipment to support both Avid's business opportunities and our internal product development efforts. Such amount is expected to be paid during the remainder of fiscal year 2014.

#### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Changes in United States interest rates would affect the interest earned on our cash and cash equivalents, however, they would not have an effect on our outstanding capital lease, which has a fixed interest rate and term.

Based on our overall cash and cash equivalents interest rate exposure at October 31, 2013, a near-term change in interest rates, based on historical movements, would not have a material adverse effect on our financial position or results of operations.

#### ITEM 4. CONTROLS AND PROCEDURES.

We maintain 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"), that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized 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 necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

We carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of October 31, 2013, the end of the period covered by this Quarterly Report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of October 31, 2013.

There were no significant changes in our internal controls over financial reporting, during the quarter ended October 31, 2013, that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

### **PART II - OTHER INFORMATION**

#### ITEM 1. LEGAL PROCEEDINGS.

In the ordinary course of business, we are at times subject to various legal proceedings and disputes. Except as set forth below, we currently are not aware of any material litigation or other dispute nor, to management's knowledge, is any litigation or other proceeding threatened against us that collectively is expected to have a material adverse effect on our consolidated cash flows, financial condition or results of operations.

##### *Securities Class Action Lawsuit*

On September 28, 2012, three complaints were filed in the U.S. District Court for the Central District of California against us and certain of our executive officers and one consultant (collectively, the "Defendants") on behalf of certain purchasers of our common stock. The complaints have been brought as purported stockholder class actions, and, in general, include allegations that Defendants violated (i) Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder and (ii) Section 20(a) of the Exchange Act, by making materially false and misleading statements regarding the interim results of our bavituximab Phase II second-line NSCLC trial, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief. On November 27, 2012, four prospective lead plaintiffs filed motions to consolidate, appoint a lead plaintiff and appoint lead counsel. On February 5, 2013, the court consolidated the related actions with the low-numbered case (captioned *Anderson v. Peregrine Pharmaceuticals, Inc., et al.*, Case No. 12-cv-1647-PSG (FMOx)), appointed James T. Fahey as lead plaintiff, and appointed Mr. Fahey's counsel as lead counsel. The lead plaintiff filed an amended consolidated complaint on April 15, 2013. On June 14, 2013, Defendants moved to dismiss the amended consolidated complaint. On July 15, 2013, lead plaintiff filed an opposition to Defendants' motion to dismiss and separately moved to strike certain exhibits attached to Defendants' motion. On August 19, 2013 the court held a hearing on Defendants' motion to dismiss and on lead plaintiff's motion to strike. On August 23, 2013, the court issued its order granting Defendants' motion to dismiss and denying lead plaintiff's motion to strike. In its order, the court gave lead plaintiff leave to amend his complaint on or before September 16, 2013. On September 16, 2013 lead plaintiff filed his first amended complaint. On October 3, 2013, Defendants' filed a motion to dismiss the first amended complaint. Briefing on that motion concluded in early November 2013 and, on November 22, 2013, the court issued an order granting Defendants' motion to dismiss the first amended complaint. The court again granted lead plaintiff leave to file an amended complaint, which is due no later than January 22, 2014. We believe that the class action lawsuit is without merit and intend to vigorously defend the action, including seeking dismissal of any amended complaint. Due to the early stage of the proceeding, we believe that the probability of an unfavorable outcome or loss related to the proceeding and an estimate of the amount or range of loss related to the claims, if any, from an unfavorable outcome is not determinable at this time.

## Derivative Litigation

On May 9, 2013, an alleged shareholder filed, purportedly on behalf of the Company, a derivative lawsuit, captioned *Roy v. Steven W. King, et al.*, Case No. 13-cv-0741-PSG (RNBx), in the U.S. District Court for the Central District of California against certain of our executive officers and directors. The complaint asserts claims for breach of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment arising from substantially similar factual allegations as those asserted in the consolidated securities class action lawsuit, described above (the "Securities Class Action"). This case was subsequently transferred to the same court and judge handling the Securities Class Action lawsuit. On May 31, 2013, the judge issued an order staying this derivative litigation pending the final resolution of defendants' motions to dismiss in the Securities Class Action.

On October 10, 2013, a derivative and class action complaint, captioned *Michaeli v. Steven W. King, et al.*, C.A. No. 8994-VCL, was filed in the Court of Chancery of the State of Delaware against certain of our executive officers and directors. The complaint alleges that the Company's directors and executives breached their respective fiduciary duties in connection with certain purportedly improper compensation decisions made by the Company's Board of Directors during the past three fiscal years, including: (i) the grant of a stock option to Mr. King on May 4, 2012; (ii) the non-routine broad-based stock option grant to the Company's directors, executives, all other employees and certain consultants on December 27, 2012; and (iii) the payment, during the past three fiscal years, of compensation to the Company's non-employee directors. In addition, the complaint alleges that the Company's directors breached their fiduciary duty of candor by filing and seeking stockholder action on the basis of an allegedly materially false and misleading proxy statement for the Company's 2013 annual meeting of stockholders. On December 2, 2013, the Chancery Court granted the parties' stipulation to set a briefing schedule regarding defendants' response to the complaint. Pursuant to that order, defendants shall serve an answer or motion to dismiss the complaint by January 20, 2014. If defendants move to dismiss the complaint, then plaintiffs must file and serve an opposition brief by February 17, 2014, and defendants must file and serve their reply by March 3, 2014.

## Other Legal Matters

On September 24, 2012, we filed a lawsuit, captioned *Peregrine Pharmaceuticals, Inc. v. Clinical Supplies Management, Inc.*, Case No. 8:12-cv-01608 JST(AN) (C.D. Cal), against Clinical Supplies Management, Inc. ("CSM"), in the U.S. District Court for the Central District of California. In 2010, we had contracted with CSM as our third-party vendor responsible for distribution of the blinded investigational product used in our bavituximab Phase IIb second-line NSCLC trial. As part of the routine collection of data in advance of an end-of-Phase II meeting with regulatory authorities, we discovered major discrepancies between some patient sample test results and patient treatment code assignments. Consequently, we filed this lawsuit against CSM alleging breach of contract, negligence and negligence per se arising from CSM's performance of its contracted services. We are seeking monetary damages. On March 7, 2013, we and CSM submitted to the court a proposed stipulation pursuant to which the lawsuit would be stayed for up to 120 days during which time we and CSM would participate in an alternative dispute resolution process, pursuant to our contract with CSM. The proposed stipulation was approved by the court on March 8, 2013. On June 26, 2013, we and CSM engaged in an alternative dispute resolution session that did not result in any resolution of our dispute. The aforementioned stay expired on July 6, 2013. We granted CSM until July 19, 2013 to file an answer to our complaint, which CSM did on July 11, 2013. No further activity has occurred since that date.

## ITEM 1A. RISK FACTORS.

*The following risk factors below update, and should be considered in addition to, the risk factors previously disclosed by us in Part 1, Item 1A of our Annual Report on Form 10-K for the fiscal year ended April 30, 2013.*

**IF WE CANNOT OBTAIN ADDITIONAL FUNDING, OUR PRODUCT DEVELOPMENT AND COMMERCIALIZATION EFFORTS MAY BE REDUCED OR DISCONTINUED AND WE MAY NOT BE ABLE TO CONTINUE OPERATIONS OR TIMELY COMPLETE OUR PHASE III SUNRISE TRIAL.**

At October 31, 2013, we had \$44,443,000 in cash and cash equivalents. We have expended substantial funds on the research and development of our product candidates, and funding the operations of Avid. As a result, we have historically experienced negative cash flows from operations since our inception and we expect negative cash flows from operations to continue in the foreseeable future. Our net loss incurred during the six-month period ended October 31, 2013 amounted to \$15,390,000 and our net losses incurred during the past three fiscal years ended April 30, 2013, 2012 and 2011, amounted to \$29,780,000, \$42,119,000, and \$34,151,000, respectively. Therefore, unless and until we are able to generate sufficient revenues from Avid's contract manufacturing services and/or from the sale and/or licensing of our products under development, we expect such losses to continue in the foreseeable future.

Therefore, our ability to continue to fund our clinical trials and development efforts is highly dependent on the amount of cash and cash equivalents on hand combined with our ability to raise additional capital to support our future operations through one or more methods, including but not limited to, issuing additional equity or debt.

Historically, we have funded a significant portion of our operations through the issuance of equity. During the six months ended October 31, 2013, we raised \$24,277,000 in aggregate gross proceeds under an At Market Sales Issuance Agreement (as described in Note 7 to the accompanying interim unaudited condensed consolidated financial statements). With these proceeds, we currently estimate that we have sufficient cash resources to meet our anticipated cash needs to fund our operations through at least September 2014 based on our current projections, which includes projected costs associated with our pivotal Phase III SUNRISE trial, projected cash inflows under signed contracts with existing customers of Avid and assuming we raise no additional capital from the capital markets or other potential sources.

However, our ability to continue to fund our clinical trials and development efforts in future years, including costs to fund our pivotal Phase III SUNRISE trial beyond September 2014, is highly dependent on our ability to raise additional capital to support our future operations through one or more methods, including but not limited to, financing our operations through the issuance of equity, securing new funding through the issuance of debt, licensing or partnering our products in development, or increasing revenue from our wholly-owned subsidiary, Avid. While we will continue to explore these potential opportunities, we may not be successful in securing debt financing, licensing or partnering our products in development, or generating additional revenue from Avid to complete the research, development, and clinical testing of our product candidates. Even if we are successful in obtaining debt financing, it may involve restrictive covenants on the operation of our business and require significant interest payments.

With respect to our ability to raise additional capital from the issuance of equity, as of October 31, 2013, we have an effective shelf registration statement on Form S-3, under which we may issue, from time to time, in one or more offerings, shares of our common stock for gross proceeds of up to \$112,351,000. However, our ability to raise additional capital in the equity markets is dependent on a number of factors, including, but not limited to, the market demand for our common stock. The market demand or liquidity of our common stock is subject to a number of risks and uncertainties, including but not limited to, negative economic conditions, adverse market conditions, adverse clinical trial results and significant delays in one or more clinical trials. If our ability to access the capital markets becomes severely restricted, it could have a negative impact on our business plans, including our clinical trial programs and other research and development activities. In addition, even if we are able to raise additional capital, it may not be at a price or on terms that are favorable to us.

**WE HAVE HAD SIGNIFICANT LOSSES AND WE ANTICIPATE FUTURE LOSSES.**

We have incurred net losses in most fiscal years since we began operations in 1981. The following table represents net losses incurred for the six months ended October 31, 2013 and for each of the past three fiscal years:

	<u>Net Loss</u>
Six months ended October 31, 2013 (unaudited)	\$ 15,390,000
Fiscal Year 2013	\$ 29,780,000
Fiscal Year 2012	\$ 42,119,000
Fiscal Year 2011	\$ 34,151,000

As of October 31, 2013, we had an accumulated deficit of \$383,294,000. While we expect to continue to generate revenue from Avid's contract manufacturing services, in order to achieve and sustain profitable operations, we must successfully develop and obtain regulatory approval for our products, either alone or with others, and must also manufacture, introduce, market and sell our products. The costs associated with clinical trials and product manufacturing is very expensive and the time frame necessary to achieve market success for our products is long and uncertain. Furthermore, as evidenced by the increase in our net loss for fiscal years 2011 and 2012, during which we were conducting the majority of our Phase IIb trial in NSCLC, the costs associated with advanced stage clinical trials can significantly increase due, in part, to expanded patient populations and the cost to prepare for potential commercialization. In addition, we anticipate initiating our Phase III SUNRISE trial by December 31, 2013, and therefore expect our net losses for fiscal year 2014 to exceed our net loss for fiscal year 2013. We do not expect to generate product or royalty revenues for at least the next two years, and we may never generate product and/or royalty revenues sufficient to become profitable or to sustain profitability.

**THE SALE OF SUBSTANTIAL SHARES OF OUR COMMON STOCK MAY DEPRESS OUR STOCK PRICE.**

As of October 31, 2013, there were 160,248,742 shares of our common stock outstanding. Substantially all of these shares are eligible for trading in the public market, subject in some cases to volume and other limitations. The market price of our common stock may decline if our common stockholders sell a large number of shares of our common stock in the public market, or the market perceives that such sales may occur.

We could also issue up to 29,858,569 additional shares of our common stock that are reserved for future issuance under our stock incentive plans, employee stock purchase plan, and exercise of outstanding warrants, as further described in the following table:

	<b>Number of Shares Reserved</b>
Common shares reserved for issuance under outstanding option grants and common shares available for issuance under our stock incentive plans	26,306,989
Common shares reserved for and available for issuance under our Employee Stock Purchase Plan	3,176,777
Common shares issuable upon exercise of outstanding warrants	374,803
Total shares of common stock reserved for issuance	<u>29,858,569</u>

In addition, the above table does not include shares of common stock we could potentially issue from time to time, in one or more offerings, under our current effective shelf registration statements in exchange for remaining aggregate gross proceeds of up to \$112,351,000 as of October 31, 2013.

Of the total options and warrants outstanding as of October 31, 2013, 9,225,257 would be considered dilutive to stockholders because we would receive an amount per share, which is less than the market price of our common stock at October 31, 2013.

In addition, we will need to raise substantial additional capital in the future to fund our operations, including our Phase III SUNRISE trial. If we raise additional funds by issuing equity securities, the market price of our securities may decline and our existing stockholders may experience significant dilution.

**WE AND CERTAIN OF OUR EXECUTIVE OFFICERS AND ONE CONSULTANT HAVE BEEN NAMED AS DEFENDANTS IN LITIGATION THAT COULD RESULT IN SUBSTANTIAL COSTS AND DIVERT MANAGEMENT'S ATTENTION.**

On September 28, 2012, three complaints were filed in the U.S. District Court for the Central District of California against us and certain of our executive officers and one consultant (collectively, the "Defendants") on behalf of certain purchasers of our common stock. The complaints were brought as purported stockholder class actions, and, in general, include allegations that Defendants violated (i) Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder and (ii) Section 20(a) of the Exchange Act, by making materially false and misleading statements regarding the interim results of our baviximab Phase II second-line NSCLC trial, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief. On February 5, 2013, the court appointed James T. Fahey as lead plaintiff in the action. The lead plaintiff filed an amended consolidated complaint on April 15, 2013. On June 14, 2013, Defendants moved to dismiss the amended consolidated complaint. On July 15, 2013, lead plaintiff filed an opposition to Defendants' motion to dismiss and separately moved to strike certain exhibits attached to Defendants' motion. On August 19, 2013 the court held a hearing on Defendants' motion to dismiss and on lead plaintiff's motion to strike. On August 23, 2013, the court issued its order granting Defendants' motion to dismiss and denying lead plaintiff's motion to strike. In its order, the court gave lead plaintiff leave to amend his complaint on or before September 16, 2013. On September 16, 2013 lead plaintiff filed his first amended complaint. On October 3, 2013, Defendants' filed a motion to dismiss the first amended complaint. Briefing on the motion concluded in early November 2013 and, on November 22, 2013, the court issued an order granting Defendants' motion to dismiss the first amended complaint. The court again granted lead plaintiff leave to file an amended complaint, which is due no later than January 22, 2014.

There is no guarantee that we will be successful on our motion to dismiss, or in defending should it proceed to trial, the amended consolidated lawsuit. Also, our insurance coverage may be insufficient, our assets may be insufficient to cover any amounts that exceed our insurance coverage, and we may have to pay damage awards or otherwise may enter into settlement arrangements in connection with such claims. A settlement of the lawsuit could involve the issuance of common stock or other equity, which may dilute your ownership interest. Any payments or settlement arrangements could have material adverse effects on our business, operating results, financial condition or your ownership interest. Even if the lead plaintiff's claims are not successful, this litigation could result in substantial costs and significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results, financial condition or partnering efforts. In addition, such consolidated lawsuit may make it more difficult to finance our operations, obtain certain types of insurance (including directors' and officers' liability insurance), and attract and retain qualified executive officers, other employees and directors.

**OUR HIGHLY VOLATILE STOCK PRICE AND TRADING VOLUME MAY ADVERSELY AFFECT THE LIQUIDITY OF OUR COMMON STOCK.**

The market price of our common stock and the market prices of securities of companies in the biotechnology sector have generally been highly volatile and are likely to continue to be highly volatile.

The following table shows the high and low sales price and trading volume of our common stock for each of the last twelve (12) fiscal quarters ended October 31, 2013:

	Common Stock Sales Price		Common Stock Daily Trading Volume (000's omitted)	
	High	Low	High	Low
Quarter Ended October 31, 2013	\$1.54	\$1.25	4,968	409
Quarter Ended July 31, 2013	\$2.06	\$1.11	21,624	682
Quarter Ended April 30, 2013	\$2.43	\$1.20	30,965	811
Quarter Ended January 31, 2013	\$2.78	\$0.69	62,489	739
Quarter Ended October 31, 2012	\$5.50	\$0.67	68,511	563
Quarter Ended July 31, 2012	\$1.89	\$0.42	11,875	276
Quarter Ended April 30, 2012	\$1.14	\$0.39	7,397	282
Quarter Ended January 31, 2012	\$1.53	\$0.85	7,162	138
Quarter Ended October 31, 2011	\$1.88	\$0.95	2,450	110
Quarter Ended July 31, 2011	\$2.48	\$1.56	1,012	144
Quarter Ended April 30, 2011	\$2.74	\$2.05	929	152
Quarter Ended January 31, 2011	\$3.10	\$1.46	3,434	105

The market price of our common stock may be significantly impacted by many factors, including, but not limited to:

- the success or failure of our internal drug development efforts;
- positive or negative data reported on programs in clinical trials we or our investigators are conducting;
- announcements of technological innovations or new commercial products by us or our competitors;
- uncertainties about our ability to continue to fund our operations beyond September 2014, including our Phase III SUNRISE trial;
- significant changes in our financial results or that of our competitors, including our ability to continue as a going concern;
- the offering and sale of shares of our common stock, either sold at market prices or at a discount under an equity transaction;
- significant changes in our capital structure;
- published reports by securities analysts;
- announcements of partnering transactions, licensing agreements, joint ventures, strategic alliances, and any other transaction that involves the development, sale or use of our technologies or competitive technologies;
- developments and/or disputes concerning our patent or other proprietary rights;
- regulatory developments, including possible delays, and product safety concerns;
- outcomes of significant litigation, disputes and other legal or regulatory proceedings;
- general stock trends in the biotechnology and pharmaceutical industry sectors;
- public concerns as to the safety and effectiveness of our products;
- economic trends and other external factors, including but not limited to, interest rate fluctuations, economic recession, inflation, foreign market trends, national crisis, and disasters; and
- healthcare reimbursement reform and cost-containment measures implemented by government agencies.



These and other external factors have caused and may continue to cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock, and may otherwise negatively affect the liquidity of our common stock.

**THE LIQUIDITY OF OUR COMMON STOCK WILL BE ADVERSELY AFFECTED IF OUR COMMON STOCK IS DELISTED FROM THE NASDAQ CAPITAL MARKET.**

Our common stock is traded on The NASDAQ Capital Market. To maintain inclusion on The NASDAQ Capital Market, we must continue to meet the following six listing requirements:

1. Stockholders' equity of at least \$2,500,000 or market value of at least \$35,000,000 or net income of at least \$500,000 in either our latest fiscal year or in two of our last three fiscal years;
2. Public float of at least 500,000 shares;
3. Market value of our public float of at least \$1,000,000;
4. A minimum closing bid price of \$1.00 per share of common stock, without falling below this minimum bid price for a period of thirty consecutive trading days;
5. At least two market makers; and
6. At least 300 stockholders, each holding at least 100 shares of common stock.

If our common stock were ever delisted, we would apply to have our common stock quoted on the OTCQX, the world's largest interdealer quotation system, which is operated by OTC Market Groups, Inc. Upon any such delisting, our common stock would become subject to the regulations of the SEC relating to the market for penny stocks. A penny stock, as defined by the Penny Stock Reform Act, is any equity security not traded on a national securities exchange that has a market price of less than \$5.00 per share. The penny stock regulations generally require that a disclosure schedule explaining the penny stock market and the risks associated therewith be delivered to purchasers of penny stocks and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. The broker-dealer must make a suitability determination for each purchaser and receive the purchaser's written agreement prior to the sale. In addition, the broker-dealer must make certain mandated disclosures, including the actual sale or purchase price and actual bid offer quotations, as well as the compensation to be received by the broker-dealer and certain associated persons. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit your ability to sell your securities in the secondary market.

**WE DO NOT INTEND TO PAY DIVIDENDS ON OUR COMMON STOCK SO ANY RETURNS WILL BE LIMITED TO THE VALUE OF OUR STOCK.**

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

**SUCCESSFUL DEVELOPMENT OF OUR PRODUCT CANDIDATES IS UNCERTAIN. TO DATE, NO REVENUES HAVE BEEN GENERATED FROM THE COMMERCIAL SALE OF OUR PRODUCT CANDIDATES AND OUR PRODUCT CANDIDATES MAY NOT GENERATE REVENUES IN THE FUTURE.**

Our development of current and future product candidates is subject to the risks of failure inherent in the development of new pharmaceutical products and products based on new technologies. These risks include:

- delays in product development, clinical testing or manufacturing;
- unplanned expenditures in product development, clinical testing or manufacturing;
- failure in clinical trials or failure to receive regulatory approvals;
- emergence of superior or equivalent products;
- inability to manufacture on our own, or through others, product candidates on a commercial scale;
- inability to market products due to third party proprietary rights; and
- failure to achieve market acceptance.

Because of these risks, our research and development efforts or those of our partners may not result in any commercially viable products. If significant portions of these development efforts are not successfully completed, required regulatory approvals are not obtained, or any approved products are not commercially successful, our business, financial condition and results of operations may be materially harmed.

Because we have not begun the commercial sale of any of our product candidates, our revenue and profit potential is unproven and our operating history makes it difficult for an investor to evaluate our business and prospects. Our technology may not result in any meaningful benefits to our current or potential partners. No revenues have been generated from the commercial sale of our product candidates, and our products may not generate revenues in the future. Our business and prospects should be considered in light of the heightened risks and unexpected expenses and problems we may face as a company in an early stage of product development in an extremely competitive and rapidly evolving industry.

**WE ARE PRIMARILY FOCUSING OUR ACTIVITIES AND RESOURCES ON THE DEVELOPMENT OF BAVITUXIMAB AND DEPEND ON ITS SUCCESS.**

We are focusing most of our near-term research and development activities and resources on bavituximab, and we believe a significant portion of the value of our Company relates to our ability to develop this drug candidate. The development of bavituximab is subject to many risks, including the risks discussed in other risk factors. If the results of clinical trials of bavituximab, including our Phase III SUNRISE trial, the regulatory decisions affecting bavituximab, the anticipated or actual timing and plan for commercializing bavituximab, or, ultimately, the market acceptance of bavituximab do not meet our, your, analysts or others expectations, the market price of our common stock could be adversely affected.

**OUR PRODUCT DEVELOPMENT EFFORTS MAY NOT BE SUCCESSFUL.**

Our product candidates have not received regulatory approval and are generally in research, preclinical and various clinical stages of development. If the results from any of the clinical trials are not positive, those results may adversely affect our ability to raise additional capital or obtain regulatory approval to conduct additional clinical trials, which will affect our ability to continue full-scale research and development for our antibody technologies. In addition, our product candidates may take longer than anticipated to progress through clinical trials, or patient enrollment in the clinical trials may be delayed or prolonged significantly, thus delaying the clinical trials. Patient enrollment is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to the clinical sites, competing studies of other investigational products, and the inclusion and exclusion eligibility criteria for the study. In addition, because our Cotara product candidate represents a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in any future clinical study.

**CLINICAL TRIALS REQUIRED FOR OUR PRODUCT CANDIDATES ARE EXPENSIVE AND TIME CONSUMING, AND THEIR OUTCOME IS UNCERTAIN.**

In order to obtain FDA approval to market a new drug product, we or our potential partners must demonstrate proof of safety and efficacy in humans. To meet these requirements, we or our potential partners will have to conduct extensive preclinical testing and “adequate and well-controlled” clinical trials. Conducting clinical trials is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and often can be several years or more per trial. Delays associated with products for which we are directly conducting preclinical or clinical trials may cause us to incur additional operating expenses. Moreover, we may continue to be affected by delays associated with the preclinical testing and clinical trials of certain product candidates conducted by our partners over which we have no control. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example:

- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations (“CROs”), and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- slower than expected rates of patient recruitment due to narrow screening requirements;
- the inability of patients to meet FDA or other regulatory authorities imposed protocol requirements;
- the inability to retain patients who have initiated a clinical trial but may be prone to withdraw due to various clinical or personal reasons, or who are lost to further follow-up;
- the inability to manufacture sufficient quantities of qualified materials under current good manufacturing practices, or cGMPs, for use in clinical trials;
- shortages of chemotherapy or other drugs used in clinical trials in combination with bavituximab;
- the need or desire to modify our manufacturing processes;
- the inability to adequately observe patients after treatment;
- changes in regulatory requirements for clinical trials;
- the lack of effectiveness during the clinical trials;
- unforeseen safety issues;
- delays, suspension, or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and
- government or regulatory delays or “clinical holds” requiring suspension or termination of the trials.

Even if we obtain positive results from preclinical or initial clinical trials, we may not achieve the same success in future trials. Clinical trials may not demonstrate statistically sufficient safety and effectiveness to obtain the requisite regulatory approvals for product candidates employing our technology.

Clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for any of our product candidates. We expect to commence new clinical trials from time to time in the course of our business as our product development work continues. The failure of clinical trials to demonstrate safety and effectiveness for our desired indications could harm the development of that product candidate as well as other product candidates. Any change in, or termination of, our clinical trials could materially harm our business, financial condition and results of operations.

**WE RELY ON THIRD-PARTIES TO CONDUCT OUR CLINICAL TRIALS AND MANY OF OUR PRECLINICAL STUDIES. IF THOSE PARTIES DO NOT SUCCESSFULLY CARRY OUT THEIR CONTRACTUAL DUTIES OR MEET EXPECTED DEADLINES, OUR DRUG CANDIDATES MAY NOT ADVANCE IN A TIMELY MANNER OR AT ALL.**

In the course of our discovery, preclinical testing and clinical trials, we rely on third parties, including universities, investigators and clinical research organizations, to perform critical services for us. For example, we rely on third parties to conduct our clinical trials and many of our preclinical studies. CROs and investigators are responsible for many aspects of the trials, including finding and enrolling patients for testing and administering the trials. Certain of our clinical trials are blind or double-blind, including our Phase III SUNRISE trial. If the trial is blind, management does not have access to information regarding the trials’ administration and progress. We therefore must rely on third parties to conduct our clinical trials, but their failure to comply with all regulatory and contractual requirements, or to perform their services in a timely and acceptable manner, may compromise our clinical trials in particular or our business in general. Although we rely on these third parties to conduct our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. These third parties may not be available when we need them or, if they are available, may not comply with all regulatory and contractual requirements or may not otherwise perform their services in a timely or acceptable manner. Any failings by these third parties may compromise our clinical trials in particular or our business in general. Similarly, we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. These independent third parties may also have relationships with other commercial entities, some of which may compete with us. For example, if such third parties fail to perform their obligations in compliance with our clinical trial protocols, our clinical trials may not meet regulatory requirements or may need to be repeated. As a result of our dependence on third parties, we may face delays or failures outside of our direct control, as evidenced by the major discrepancies in treatment group coding by an independent third-party vendor responsible for distribution of blinded investigational product used in our bavituximab Phase II NSCLC trial. These risks also apply to the development activities of our collaborators, and we do not control our collaborators’ research and development, clinical trials or regulatory activities. We do not expect any drugs resulting from our collaborators’ research and development efforts to be commercially available for many years, if ever.

In addition, we have prepaid research and development expenses to third parties that have been deferred and capitalized as pre-payments to secure the receipt of future preclinical and clinical research and development services. These pre-payments are recognized as an expense in the period that the services are performed. We assess our prepaid research and development expenses for impairment when events or changes in circumstances indicate that the carrying amount of the prepaid expense may not be recoverable or provide a future economic benefit, including the risk of third party nonperformance. If there are indicators that the third parties are unable to perform the research and development services, we may be required to take an impairment charge.

**WE DO NOT HAVE EXPERIENCE AS A COMPANY CONDUCTING LARGE-SCALE CLINICAL TRIALS, OR IN OTHER AREAS REQUIRED FOR THE SUCCESSFUL COMMERCIALIZATION AND MARKETING OF OUR PRODUCT CANDIDATES.**

Results from early stage clinical trials of bavituximab and Cotara may not be indicative of successful outcomes in later stage trials. Negative or limited results from any current or future clinical trial could delay or prevent further development of our product candidates, which would adversely affect our business.

We have no experience as a company in conducting large-scale, late-stage clinical trials, and our experience with early-stage clinical trials with small numbers of patients is limited. In part because of this limited experience, we cannot be certain that planned clinical trials will begin or be completed on time, if at all. Large-scale trials would require significant additional financial and management resources, and reliance on third-party clinical investigators, CROs or consultants. Relying on third-party clinical investigators or CROs may force us to encounter delays that are outside of our control. Any such delays could have a material adverse effect on our business.

We also do not currently have marketing, sales and distribution capabilities for our product candidates. Developing an internal sales and distribution capability would be an expensive and time-consuming process. We may enter into agreements with third parties that would be responsible for marketing and distribution. However, these third parties may not be capable of successfully selling any of our product candidates. The inability to commercialize and market our product candidates could materially affect our business.

**FAILURE TO RECRUIT, ENROLL AND RETAIN PATIENTS FOR CLINICAL TRIALS MAY CAUSE THE DEVELOPMENT OF OUR PRODUCT CANDIDATES TO BE DELAYED OR DEVELOPMENT COSTS TO INCREASE SUBSTANTIALLY.**

We have experienced, and expect to experience in the future, delays in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of subjects depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- competition for patients by clinical trial programs for other competitive treatments.

Our clinical trials compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of subjects available to us, because some patients who might have opted to enroll in our trials opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which reduces the number of subjects who are available for our clinical trials in such clinical trial site. Delays in patient enrollment in the future as a result of these and other factors may result in increased costs or may affect the timing or outcome of our clinical trials, which could prevent us from completing these trials and adversely affect our ability to advance the development of our product candidates.

**PATIENT ENROLLMENT AND PATIENT CARE PROVIDED AT INTERNATIONAL CLINICAL SITES MAY BE DELAYED OR OTHERWISE ADVERSELY IMPACTED BY SOCIAL, POLITICAL AND ECONOMIC FACTORS AFFECTING THE PARTICULAR FOREIGN COUNTRY.**

In the past we have conducted, and intend to conduct in connection with our Phase III SUNRISE trial, clinical trials globally including clinical sites in Eastern Europe, Asia-Pacific and other countries. Our ability to successfully initiate, enroll and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the conduct of clinical trials and/or health care reimbursement;
- our inability to locate qualified local consultants, physicians, and partners;
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical products and treatment; and
- general geopolitical risks, such as political and economic instability, and changes in diplomatic and trade relations.

Because we intend to conduct clinical trials in foreign countries, any disruption to our international clinical trial sites could significantly delay or jeopardize our product development efforts.

**SUCCESS IN EARLY CLINICAL TRIALS MAY NOT BE INDICATIVE OF RESULTS OBTAINED IN LATER TRIALS.**

A number of new drugs and biologics have shown promising results in initial clinical trials, but subsequently failed to establish sufficient safety and effectiveness data to obtain necessary regulatory approvals. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval.

Data from our preclinical studies and Phase I and Phase II clinical trials should not be relied upon as evidence that later or larger-scale clinical trials will succeed. The Phase I studies we have completed to date have been designed to primarily assess safety in a small number of patients. In addition, the results we have obtained in the Phase II trials may not predict results for any future studies and may not predict future therapeutic benefit of our drug candidates. We will be required to demonstrate through larger-scale clinical trials that baviximab and Cotara are safe and effective for use in a diverse population before we can seek regulatory approval for their commercial sale. There is typically an extremely high rate of attrition from the failure of drug candidates proceeding through clinical trials.

In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development.

**IF WE SUCCESSFULLY DEVELOP PRODUCTS BUT THOSE PRODUCTS DO NOT ACHIEVE AND MAINTAIN MARKET ACCEPTANCE, OUR BUSINESS WILL NOT BE PROFITABLE.**

Even if the FDA or other regulatory authorities approve baviximab, Cotara, or any future product candidate for commercial sale, the degree of market acceptance of any approved product candidate by physicians, healthcare professionals and third-party payors and our profitability and growth will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- changes in the standard of care for the targeted indication;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability, cost and potential advantages of alternative treatments;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or our partners' sales and marketing strategy;
- the product labeling or product insert required by the FDA or regulatory authority in other countries; and
- our ability to obtain sufficient third-party insurance coverage or reimbursement.

In addition, if baviximab, Cotara, or any future product candidate that we discover and develop does not provide a treatment regimen that is more beneficial than the current standard of care or otherwise provide patient benefit, that product likely will not be accepted favorably by the market. If any products we may develop do not achieve market acceptance, then we may not generate sufficient revenue to achieve or maintain profitability.

In addition, even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

**IF WE DO NOT ESTABLISH ADDITIONAL COLLABORATIONS, WE MAY HAVE TO ALTER OUR DEVELOPMENT PLANS.**

Our drug development programs and potential commercialization of our drug candidates will require substantial additional cash to fund expenses. We either own or we in-licensed all rights to our two lead drug candidates, bavituximab and Cotara, and are fully responsible for the associated development costs. Our strategy continues to include the potential of selectively collaborating with leading pharmaceutical and biotechnology companies to assist us in furthering development and potential commercialization of some of our drug candidates and research programs. We may enter into one or more of such collaborations in the future, especially for target indications in which the potential collaborator has particular therapeutic expertise or that involve a large, primary care market that must be served by large sales and marketing organizations or for markets outside of North America. We face significant competition in seeking appropriate collaborators and these collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on acceptable terms, or at all. Even if we successfully enter into a collaboration, our partner may not perform its contractual obligations or may terminate the agreement. If that were to occur, we may have to curtail the development of a particular drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our drug candidates to market and generate product revenue.

**HEALTHCARE REFORM MEASURES AND OTHER STATUTORY OR REGULATORY CHANGES COULD ADVERSELY AFFECT OUR BUSINESS.**

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our business. For example, the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the “ACA”), enacted in March 2010, substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. With regard to pharmaceutical products, among other things, the ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare D program.

The pharmaceutical and biotechnology industries are subject to extensive regulation, and from time to time legislative bodies and governmental agencies consider changes to such regulations that could have significant impact on industry participants. For example, in light of certain highly-publicized safety issues regarding certain drugs that had received marketing approval, the U.S. Congress has considered various proposals regarding drug safety, including some which would require additional safety studies and monitoring and could make drug development more costly. We are unable to predict what additional legislation or regulation, if any, relating to safety or other aspects of drug development may be enacted in the future, or what effect such legislation or regulation would have on our business.

**THE COVERAGE AND REIMBURSEMENT STATUS OF NEWLY APPROVED DRUGS IS UNCERTAIN, AND FAILURE TO OBTAIN ADEQUATE COVERAGE AND REIMBURSEMENT COULD LIMIT OUR ABILITY TO MARKET BAVITUXIMAB AND COTARA AND MAY DECREASE OUR ABILITY TO GENERATE REVENUE.**

There is significant uncertainty related to the third party coverage and reimbursement of newly approved drugs both nationally and internationally. The commercial success of bavituximab, Cotara, and any other of our future products, if any, in both domestic and international markets depends on whether third-party coverage and reimbursement is available for the ordering of our future products by the medical profession for use by their patients. Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to manage healthcare costs by limiting both coverage and the level of reimbursement of new drugs and, as a result, they may not cover or provide adequate payment for our future products. These payors may not view our future products as cost-effective, and reimbursement may not be available to consumers or may not be sufficient to allow our future products to be marketed on a competitive basis. Likewise, legislative or regulatory efforts to control or reduce healthcare costs or reform government healthcare programs could result in lower prices or rejection of our future products. Changes in coverage and reimbursement policies or healthcare cost containment initiatives that limit or restrict reimbursement for our future products may reduce any future product revenue.

**FAILURE TO OBTAIN REGULATORY APPROVAL IN FOREIGN JURISDICTIONS WILL PREVENT US FROM MARKETING BAVITUXIMAB ABROAD.**

We intend to market bavituximab in international markets either directly or through a potential future collaboration partner, if any. In order to market bavituximab in the European Union, Canada, Japan and many other foreign jurisdictions, we or a potential future collaboration partner must obtain separate regulatory approvals. We have, and potential future collaboration partners may have, had limited interactions with foreign regulatory authorities, and the approval procedures vary among countries and can involve additional testing at significant cost. The time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval processes may include all of the risks associated with obtaining FDA approval. In addition, in some foreign countries where we may not have conducted clinical studies (or treated a sufficient number of patients), the applicable foreign regulatory agency may require us to conduct additional studies in its country to establish the safety of our drug in that patient population, which could delay the approval process in that foreign country. We or a potential future collaboration partner may not obtain foreign regulatory approvals on a timely basis, if at all. We or a potential future collaboration partner may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize bavituximab or any other future products in any market.

**FOREIGN GOVERNMENTS OFTEN IMPOSE STRICT PRICE CONTROLS, WHICH MAY ADVERSELY AFFECT OUR FUTURE PROFITABILITY.**

We intend to seek approval to market bavituximab in both the U.S. and foreign jurisdictions either directly or through a potential future collaboration partner. If we or a potential future collaboration partner obtain approval in one or more foreign jurisdictions, we or a potential future collaboration partner will be subject to rules and regulations in those jurisdictions relating to bavituximab. In some foreign countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug candidate. To obtain reimbursement or pricing approval in some countries, we or a potential future collaboration partner may be required to conduct a clinical trial that compares the cost-effectiveness of bavituximab to other available therapies. If reimbursement of bavituximab is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

**IF WE CANNOT LICENSE OR SELL COTARA, IT MAY BE DELAYED OR NEVER BE FURTHER DEVELOPED IN THE U.S.**

We have completed a single-arm Phase II study with Cotara for the treatment of brain cancer. In our most recent Phase II open-label, multicenter trial, 41 patients with GBM at first relapse were enrolled and received a single-treatment with Cotara. Median overall survival for patients treated with Cotara was 9.3 months. Based on these data and data from earlier clinical studies, in December 2012 we reached an agreement with the FDA on the design of a single pivotal trial to potentially support product registration for Cotara. With this clear clinical path forward, since December 2012 we have been actively pursuing a licensing or funding partner to further advance the program. In the event we are not able to secure a partnership for the program in the U.S., we may not be able to advance the project past its current stage of development. Because there are a limited number of companies, which have the financial resources, the internal infrastructure, the technical capability and the marketing infrastructure to develop and market a radiopharmaceutical-based oncology drug, we may not secure a suitable partner for Cotara. Furthermore, we cannot ensure that if we do secure a suitable licensing partner for the program, the financial terms that they propose will be acceptable to us.

**OBTAINING FAST TRACK DESIGNATION FROM THE FDA FOR OUR DRUG CANDIDATE COTARA DOES NOT GUARANTEE FASTER APPROVAL.**

We received Fast Track designation for our drug candidate Cotara for the treatment of GBM. Fast track designation is a process designed to facilitate the development and expedite the review of new drugs intended to treat serious or life-threatening diseases or conditions and that have the potential to address an unmet medical need for such disease or condition. Fast Track designation applies to the product and the specific indication for which it is being studied. Once a Fast Track designation is obtained, the FDA may consider for review on a rolling basis sections of the New Drug Application (“NDA”) before the complete application is submitted if the applicant provides and the FDA approves a schedule for the submission of the sections of the NDA and the applicant pays applicable user fees upon submission of the first section of the NDA. However, the time period specified in the Prescription Drug User Fee Act, which governs the time period goals the FDA has committed to reviewing an application, does not begin until the complete application is accepted for filing. Although we received Fast Track designation for Cotara, the FDA may later decide that Cotara no longer meets the conditions for qualification. In addition, Fast Track designation may not provide us with a material commercial advantage.

**OUR MANUFACTURING FACILITIES MAY NOT CONTINUE TO MEET REGULATORY REQUIREMENTS AND HAVE LIMITED CAPACITY.**

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured comply with cGMP requirements. To be successful, our therapeutic products must be manufactured for development and, following approval, in commercial quantities, in compliance with regulatory requirements and at acceptable costs. Currently, we manufacture all preclinical and clinical material through Avid, our wholly-owned subsidiary. While we believe our current facilities are adequate for the manufacturing of product candidates for clinical trials, our facilities may not be adequate to produce sufficient quantities required for commercialization.

In order to prepare for commercialization, if it is approved for sale, we may need to manufacture bavituximab in larger quantities beyond our current capacity. We may not be able to successfully increase the manufacturing capacity for bavituximab, whether at Avid or in collaboration with third-party manufacturers, in a timely or cost-effective manner or at all. Significant scale-up of manufacturing is a lengthy process and may require additional validation studies, which are costly and which the FDA must review and approve. In addition, quality issues may arise during those scale-up activities because of the inherent properties of monoclonal antibodies, like bavituximab. If we are unable to successfully scale-up manufacture of bavituximab in sufficient quality and quantity, whether at Avid or a third-party manufacturer, the development of bavituximab and its regulatory approval or commercial launch may be delayed or there may be a shortage in supply, which could significantly harm our business. If we engage a third-party manufacturer, we would need to transfer our technology to that third-party manufacturer and gain FDA approval, potentially causing delays in product delivery. In addition, if we use a third-party manufacturer, it may not perform as agreed or may terminate its agreement with us.

We may also encounter problems with the following:

- production yields;
- possible facility contamination;
- quality control and quality assurance programs;
- shortages of qualified personnel;
- compliance with FDA or other regulatory authorities regulations, including the demonstration of purity and potency;
- changes in FDA or other regulatory authorities requirements;
- production costs; and/or
- development of advanced manufacturing techniques and process controls.

In addition, we or any third-party manufacturer will be required to register the manufacturing facilities with the FDA and other regulatory authorities, provided it had not already registered. The facilities will be subject to inspections confirming compliance with cGMP or other regulations. If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

**IF WE USE HAZARDOUS AND BIOLOGICAL MATERIALS IN A MANNER THAT CAUSES INJURY OR VIOLATES APPLICABLE LAW, WE MAY BE LIABLE FOR DAMAGES.**

Our clinical trials, research and development activities and manufacturing operations involve the controlled use of hazardous materials and chemicals. We are subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of hazardous materials and chemicals. Although we believe that our procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials or chemicals. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.



**WE MAY HAVE SIGNIFICANT PRODUCT LIABILITY EXPOSURE BECAUSE WE MAINTAIN ONLY LIMITED PRODUCT LIABILITY INSURANCE.**

We face an inherent business risk of exposure to product liability claims in the event that the administration of one of our drugs during a clinical trial adversely affects or causes the death of a patient. Although we maintain product liability insurance for clinical studies in the amount of \$5,000,000 per occurrence or \$5,000,000 in the aggregate on a claims-made basis, this coverage may not be adequate. Product liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, if at all. Our inability to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims in excess of our insurance coverage, if any, or a product recall, could negatively impact our financial position and results of operations.

In addition, the contract manufacturing services that we offer through Avid expose us to an inherent risk of liability as the antibodies or other substances manufactured by Avid, at the request and to the specifications of our customers, could possibly cause adverse effects or have product defects. We obtain agreements from our customers indemnifying and defending us from any potential liability arising from such risk. However, these indemnification agreements may not adequately protect us against potential claims relating to such contract manufacturing services or protect us from being named in a possible lawsuit. Although Avid has procured insurance coverage, we may not be able to maintain our existing coverage or obtain additional coverage on commercially reasonable terms, or at all, or such insurance may not provide adequate coverage against all potential claims to which we might be exposed. A partially successful or completely uninsured claim against Avid would have a material adverse effect on our consolidated operations.

**OUR RESEARCH AND DEVELOPMENT ACTIVITIES RELY ON TECHNOLOGY LICENSED FROM THIRD PARTIES, AND TERMINATION OF ANY OF THOSE LICENSES WOULD RESULT IN LOSS OF SIGNIFICANT RIGHTS TO DEVELOP AND MARKET OUR PRODUCTS, WHICH WOULD IMPAIR OUR BUSINESS, PROSPECTS, FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

We have been granted rights to a variety of technologies necessary for our research and development activities from third parties through license agreements. Each license generally may be terminated by the licensor if we fail to perform our obligations under the agreement, including obligations to develop the drug candidates or technologies under license. If terminated, we would lose the right to develop the drug candidates, which could adversely affect our business, prospects, financial condition and results of operations. The license agreements also generally require us to meet specified milestones or show reasonable diligence in development of the technology. If disputes arise over the definition of these requirements or whether we have satisfied the requirements in a timely manner, or if any other obligations in the license agreements are disputed by the other party, the other party could terminate the agreement, and we could lose our rights to develop the licensed technology.

In addition, if new technology is developed from these licenses, we may be required to negotiate certain key financial and other terms, such as milestone and royalty payments, for the licensing of this future technology with the third party licensors, and it might not be possible to obtain any such license on terms that are satisfactory to us, or at all.

**IF WE ARE UNABLE TO OBTAIN, PROTECT AND ENFORCE OUR PATENT RIGHTS, WE MAY BE UNABLE TO EFFECTIVELY PROTECT OR EXPLOIT OUR PROPRIETARY TECHNOLOGY, INVENTIONS AND IMPROVEMENTS.**

Our success depends in part on our ability to obtain, protect and enforce commercially valuable patents. We try to protect our proprietary positions by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to developing our business. However, if we fail to obtain and maintain patent protection for our proprietary technology, inventions and improvements, our competitors could develop and commercialize products that would otherwise infringe upon our patents.

Our patent position is generally uncertain and involves complex legal and factual questions. Legal standards relating to the validity and scope of claims in the biotechnology and biopharmaceutical fields are still evolving. Accordingly, the degree of future protection for our patent rights is uncertain. The risks and uncertainties that we face with respect to our patents include the following:

- the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;
- the claims of any patents that issue may not provide meaningful protection;
- we may be unable to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us may not provide a competitive advantage;
- other parties may challenge patents licensed or issued to us;
- disputes may arise regarding the invention and corresponding ownership rights in inventions and know-how resulting from the joint creation or use of intellectual property by us, our licensors, corporate partners and other scientific collaborators; and
- other parties may design around our patented technologies.

**WE MAY BECOME INVOLVED IN LAWSUITS TO PROTECT OR ENFORCE OUR PATENTS THAT WOULD BE EXPENSIVE, TIME CONSUMING AND MAY LEAD TO DISCLOSURE OF OUR CONFIDENTIAL INFORMATION.**

In order to protect or enforce our patent rights, we may initiate patent litigation against third parties. In addition, we may become subject to interference or opposition proceedings conducted in patent and trademark offices to determine the priority and patentability of inventions. The defense of intellectual property rights, including patent rights through lawsuits, interference or opposition proceedings and other legal and administrative proceedings, would be costly and divert our technical and management personnel from their normal responsibilities. An adverse determination of any litigation or defense proceedings could put our pending patent applications at risk of not being issued.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. For example, during the course of this kind of litigation, confidential information may be inadvertently disclosed in the form of documents or testimony in connection with discovery requests, depositions or trial testimony. This disclosure could have a material adverse effect on our business and our financial results.

**BUSINESS DISRUPTIONS COULD SERIOUSLY HARM OUR FUTURE REVENUES AND FINANCIAL CONDITION AND INCREASE OUR COSTS AND EXPENSES.**

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we have limited insurance or are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to obtain raw materials for the manufacture of our clinical supplies and for our third party customers' products, for which we act as a contract manufacturer, could be disrupted, if the operations of these suppliers is affected by a man-made or natural disaster or other business interruption. Our corporate headquarters and manufacturing facility is located in California near major earthquake faults. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake or other natural disaster.

**WE MAY NOT BE ABLE TO COMPETE WITH OUR COMPETITORS IN THE BIOTECHNOLOGY INDUSTRY BECAUSE MANY OF THEM HAVE GREATER RESOURCES THAN WE DO AND THEY ARE FURTHER ALONG IN THEIR DEVELOPMENT EFFORTS.**

The pharmaceutical and biotechnology industry is intensely competitive and subject to rapid and significant technological change. Many of the drugs that we are attempting to discover or develop will be competing with existing therapies. In addition, we are aware of several pharmaceutical and biotechnology companies actively engaged in research and development of antibody-based products that have commenced clinical trials with, or have successfully commercialized, antibody products. Some or all of these companies may have greater financial resources, larger technical staffs and larger research budgets than we have, as well as greater experience in developing products and running clinical trials. We expect to continue to experience significant and increasing levels of competition in the future. In addition, there may be other companies which are currently developing competitive technologies and products or which may in the future develop technologies and products that are comparable or superior to our technologies and products.

Bavituximab is currently in clinical trials for the treatment of advanced solid tumors, including NSCLC. Although we are not aware of any other monoclonal antibodies in clinical development targeting PS as a potential therapy for advanced solid tumors, there are a number of possible competitors with approved or developmental targeted agents used alone or in combination with standard chemotherapy for the treatment of cancer, including but not limited to, Abraxane by Cellegene, Afatinib and Vargatef by Boehringer Ingelheim, Avastin<sup>®</sup> (bevacizumab) and onartuzumab by Roche, ganetespib by Synta Pharmaceuticals, Herceptin<sup>®</sup> (trastuzumab) by Roche, Rituxan<sup>®</sup> (rituximab) and Tarceva<sup>®</sup> (erlotinib) by OSI Pharmaceuticals, Inc. and Roche, Xalkori<sup>®</sup> (crizotinib) by Pfizer, and Yervoy<sup>®</sup> (ipilimumab) and nivolumab by Bristol-Myers Squibb Company. Additional possible competitors also exist with approved or developmental immunotherapies including but not limited to AMP-224 by GlaxoSmithKline, lambrolizumab by Merck & Co., MEDI-4736 by AstraZeneca, Necitumumab by Eli Lilly & Company, pidilizumab by Curetech, RD7466 by Roche and other Active Cellular Immunotherapy candidates by Dendreon and Astuprotimut-r by GlaxoSmithKline. There are a significant number of companies developing cancer therapeutics using a variety of targeted and non-targeted approaches. A direct comparison of these potential competitors will not be possible until bavituximab advances to later-stage clinical trials.

We are currently seeking a partner to further develop Cotara for the treatment of recurrent GBM, the most aggressive form of brain cancer. Since Cotara is a single-treatment approach that targets brain tumors from the inside out, it is a novel treatment dissimilar from other drugs approved or in development for this disease. Approved treatments for brain cancer include the Gliadel<sup>®</sup> Wafer (polifeprosan 20 with carmustine implant) from Eisai, Inc., Temodar<sup>®</sup> (temozolomide) from Merck, Avastin<sup>®</sup> (bevacizumab) from Roche, and the NovoTTF-100A System by Novocure. Gliadel<sup>®</sup> Wafers are inserted in the tumor cavity following surgical resection and releases a chemotherapeutic agent over time. Temodar<sup>®</sup> is administered orally to patients with brain cancer. Avastin<sup>®</sup> is a monoclonal antibody that targets VEGF to prevent the formation of new tumor blood vessels. The NovoTTF-100A system is a portable, wearable device that delivers an anti-mitotic, anti-cancer therapy.

In addition, some products in development may compete with Cotara should they become approved for marketing. These products include, but are not limited to: Apocept, a fully human fusion protein, being developed by Apogenix GmbH, rindopepimut, a peptide vaccine under development by Celldex, DCVax<sup>®</sup> a dendritic cell-based vaccine being developed by Northwest Biotherapeutics, Prophage a personalized vaccine by Agenus, Inc., and vitespen, a vaccine being developed by Agenus. In addition, oncology products marketed for other indications such as Nexavar<sup>®</sup> (Bayer/Amgen) are being tested in clinical trials for the treatment of brain cancer.

**AVID BIOSERVICES, INC., OUR SUBSIDIARY, IS EXPOSED TO RISKS RESULTING FROM ITS SMALL CUSTOMER BASE.**

A significant portion of Avid's revenues has historically been derived from a small number of customers. These customers typically do not enter into long-term contracts because their need for drug supply depends on a variety of factors, including the drug's stage of development, their financial resources, and, with respect to commercial drugs, demand for the drug in the market. Our results of operations could be adversely affected if revenue from any one of our primary customers is significantly reduced or eliminated.

**IF WE LOSE QUALIFIED MANAGEMENT AND SCIENTIFIC PERSONNEL OR ARE UNABLE TO ATTRACT AND RETAIN SUCH PERSONNEL, WE MAY BE UNABLE TO SUCCESSFULLY DEVELOP OUR PRODUCTS OR WE MAY BE SIGNIFICANTLY DELAYED IN DEVELOPING OUR PRODUCTS.**

Our success is dependent, in part, upon a limited number of key executive officers, each of whom is an at-will employee, and upon our scientific researchers. For example, because of his extensive understanding of our technologies and product development programs, the loss of Mr. Steven W. King, our President & Chief Executive Officer and Director, would adversely affect our development efforts and clinical trial programs during the six to twelve month period that we estimate it would take to find a qualified replacement.

We also believe that our future success will depend largely upon our ability to attract and retain highly-skilled research and development and technical personnel. We face intense competition in our recruiting activities, including competition from larger companies with greater resources. We do not know if we will be successful in attracting or retaining skilled personnel. The loss of certain key employees or our inability to attract and retain other qualified employees could negatively affect our operations and financial performance.

**WE HAVE FEDERAL AND STATE NET OPERATING LOSS (“NOL”) CARRYFORWARDS WHICH, IF WE WERE TO BECOME PROFITABLE, COULD BE USED TO OFFSET/DEFER FEDERAL AND STATE INCOME TAXES. OUR ABILITY TO USE SUCH CARRYFORWARDS TO OFFSET FUTURE TAXABLE INCOME MAY BE SUBJECT TO CERTAIN LIMITATIONS RELATED TO CHANGES IN OWNERSHIP OF OUR STOCK.**

As of April 30, 2013, we had federal and state NOL carryforwards of approximately \$266 million and \$203 million (excluding losses incurred during the six months ended October 31, 2013), respectively, expiring from 2014 to 2033. These NOL carryforwards could potentially be used to offset certain future federal and state income tax liabilities. However, utilization of NOL carryforwards may be subject to a substantial annual limitation pursuant to Section 382 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions due to ownership changes that have occurred previously or that could occur in the future. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. We performed a detailed analysis of our NOL carryforwards through April 30, 2013 and it was determined that no change in ownership had occurred. As a result of this analysis, we currently do not believe any Section 382 limitations will significantly impact our ability to offset income with available NOL carryforwards. However, future ownership changes under Section 382 may limit our ability to fully utilize these tax benefits. Any limitation may result in expiration of a portion of the carryforwards before utilization. If we were not able to utilize our carryforwards, we would be required to use our cash resources to pay taxes that would otherwise have been offset, thereby reducing our liquidity.

**OUR GOVERNANCE DOCUMENTS AND STATE LAW PROVIDE CERTAIN ANTI-TAKEOVER MEASURES WHICH WILL DISCOURAGE A THIRD PARTY FROM SEEKING TO ACQUIRE US UNLESS APPROVED BY THE BOARD OF DIRECTORS.**

We adopted a shareholder rights plan, commonly referred to as a “poison pill,” on March 16, 2006. The purpose of the shareholder rights plan is to protect stockholders against unsolicited attempts to acquire control of us that do not offer a fair price to our stockholders as determined by our Board of Directors. Under the plan, the acquisition of 15% or more of our outstanding common stock by any person or group, unless approved by our board of directors, will trigger the right of our stockholders (other than the acquirer of 15% or more of our common stock) to acquire additional shares of our common stock, and, in certain cases, the stock of the potential acquirer, at a 50% discount to market price, thus significantly increasing the acquisition cost to a potential acquirer. In addition, our certificate of incorporation and by-laws contain certain additional anti-takeover protective devices. For example,

- no stockholder action may be taken without a meeting, without prior notice and without a vote; solicitations by consent are thus prohibited;
- special meetings of stockholders may be called only by our Board of Directors; and
- our Board of Directors has the authority, without further action by the stockholders, to fix the rights and preferences, and issue shares, of preferred stock. An issuance of preferred stock with dividend and liquidation rights senior to the common stock and convertible into a large number of shares of common stock could prevent a potential acquirer from gaining effective economic or voting control.

Further, we are subject to Section 203 of the Delaware General Corporation Law, which, subject to certain exceptions, restricts certain transactions and business combinations between a corporation and a stockholder owning 15% or more of the corporation’s outstanding voting stock for a period of three years from the date the stockholder becomes a 15% stockholder.

Although we believe these provisions and our rights plan collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our Board of Directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors, which is responsible for appointing the members of our management.

**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.**

(a) Exhibits:

- |         |  |
|---------|--|
| 31.1    | Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended. *  |
| 31.2    | Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended. *  |
| 32      | Certification of Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(b)/15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350. * |
| 101.INS | XBRL Taxonomy Extension 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 Presentation Extension Linkbase Document. (*) (#)   |

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\* Filed herewith

# Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PEREGRINE PHARMACEUTICALS, INC.

Date: December 10, 2013

By: /s/ Steven W. King

Steven W. King  
President and Chief Executive Officer

Date: December 10, 2013

By: /s/ Paul J. Lytle

Paul J. Lytle  
Chief Financial Officer  
(signed both as an officer duly authorized to sign on behalf of the Registrant and Principal Financial Officer and Chief Accounting Officer)

**Certification of Chief Executive Officer**

I, Steven W. King, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Peregrine Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the periods covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: December 10, 2013

Signed: /s/ STEVEN W. KING  
Steven W. King  
President and Chief Executive Officer

**Certification of Chief Financial Officer**

I, Paul J. Lytle, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Peregrine Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the periods covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: December 10, 2013

Signed: /s/ PAUL J. LYTLE  
Paul J. Lytle  
Chief Financial Officer



## CERTIFICATION

I, Steven W. King, certify, pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, that the Quarterly Report of Peregrine Pharmaceuticals, Inc. on Form 10-Q for the quarter ended October 31, 2013 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report of Peregrine Pharmaceuticals, Inc. on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Peregrine Pharmaceuticals, Inc.

By: /s/ STEVEN W. KING  
Name: Steven W. King  
Title: President and Chief Executive Officer  
Date: December 10, 2013

I, Paul J. Lytle, certify, pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, that the Quarterly Report of Peregrine Pharmaceuticals, Inc. on Form 10-Q for the quarter ended October 31, 2013 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report of Peregrine Pharmaceuticals, Inc. on Form 10-Q fairly presents in all material respects the financial condition and results of operations of Peregrine Pharmaceuticals, Inc.

By: /s/ PAUL J. LYTLE  
Name: Paul J. Lytle  
Title: Chief Financial Officer  
Date: December 10, 2013

*A signed original of this written statement required by Section 906 has been provided to Peregrine Pharmaceuticals, Inc. and will be retained by Peregrine Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.*

*This Certification is being furnished pursuant to Rule 15(d) and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act (15 U.S.C. 78r), or otherwise subject to the liability of that section. This Certification shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.*