ACUSPHERE INC

FORM 10-Q
(Quarterly Report)

Filed 11/10/08 for the Period Ending 09/30/08

Address 99 HAYDEN AVENUE, SUITE 385
LEXINGTON, MA, 02421
Telephone 617-648-8800
CIK 0001115143
Symbol ACUS
SIC Code 2834 - Pharmaceutical Preparations
Industry Pharmaceuticals
Sector Healthcare
Fiscal Year 12/31
UNIVERSAL STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☑ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2008

☐ 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 000-50405

ACUSPHERE, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

04-3208947
(IRS Employer Identification No.)

500 Arsenal Street
Watertown, Massachusetts
(Address of principal executive offices)

02472
(Zip Code)

Registrant’s Telephone Number, Including Area Code: (617) 648-8800

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

As of November 6, 2008 there were 49,506,766 shares of the registrant’s common stock, $.01 par value per share, outstanding.
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ACUSPHERE, INC.

Form 10-Q
For the Quarterly Period Ended September 30, 2008

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## CONSOLIDATED BALANCE SHEETS

(in thousands except share data)

<table>
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<tr>
<th></th>
<th>September 30, 2008 (unaudited)</th>
<th>December 31, 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CURRENT ASSETS:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$4,112</td>
<td>$26,102</td>
</tr>
<tr>
<td>Other current assets</td>
<td>1,583</td>
<td>1,265</td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td>5,695</td>
<td>27,367</td>
</tr>
<tr>
<td><strong>PROPERTY AND EQUIPMENT:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Property and equipment, at cost</td>
<td>55,002</td>
<td>54,941</td>
</tr>
<tr>
<td>Less accumulated depreciation and amortization</td>
<td>(39,231)</td>
<td>(31,699)</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>15,771</td>
<td>23,242</td>
</tr>
<tr>
<td><strong>OTHER ASSETS</strong></td>
<td>1,334</td>
<td>1,411</td>
</tr>
<tr>
<td><strong>TOTAL ASSETS</strong></td>
<td>$22,800</td>
<td>$52,020</td>
</tr>
<tr>
<td><strong>LIABILITIES AND STOCKHOLDERS’ (DEFICIT)/EQUITY:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CURRENT LIABILITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current portion of long-term obligations</td>
<td>$10,225</td>
<td>$8,556</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>4,404</td>
<td>3,596</td>
</tr>
<tr>
<td>Current portion of deferred revenue</td>
<td>2,545</td>
<td>4,667</td>
</tr>
<tr>
<td>Current portion of deferred revenue - related party</td>
<td>750</td>
<td>0</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>882</td>
<td>1,994</td>
</tr>
<tr>
<td>Dividend payable</td>
<td>756</td>
<td>0</td>
</tr>
<tr>
<td>Derivative liability</td>
<td>64</td>
<td>13</td>
</tr>
<tr>
<td><strong>Total current liabilities</strong></td>
<td>19,626</td>
<td>18,826</td>
</tr>
<tr>
<td><strong>LONG-TERM LIABILITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-term obligations, net of current portion</td>
<td>3,246</td>
<td>9,454</td>
</tr>
<tr>
<td>Deferred revenue, net of current portion</td>
<td>1,386</td>
<td>—</td>
</tr>
<tr>
<td>Deferred revenue – related party, net of current portion</td>
<td>8,875</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total long-term liabilities</strong></td>
<td>13,507</td>
<td>9,454</td>
</tr>
<tr>
<td><strong>COMMITMENTS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>STOCKHOLDERS’ (DEFICIT)/EQUITY:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preferred stock, $0.01 par value per share</td>
<td>Authorized - 5,000,000 shares as of September 30, 2008 and December 31, 2007; Designated 6.5% convertible exchangeable -1,000,000 shares as of September 30, 2008 and December 31, 2007; issued and outstanding 480,000 shares as of September 30, 2008 and 690,000 shares as of December 31, 2007 (liquidation value $24,000,000 as of September 30, 2008)</td>
<td>5</td>
</tr>
<tr>
<td>Common stock, $0.01 par value per share</td>
<td>Authorized, 98,500,000 shares as of September 30, 2008 and December 31, 2007; issued and outstanding 48,070,622 shares as of September 30, 2008 and 46,273,945 as of December 31, 2007</td>
<td>481</td>
</tr>
<tr>
<td>Additional paid-in capital</td>
<td>358,872</td>
<td>358,141</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(369,691)</td>
<td>(334,871)</td>
</tr>
<tr>
<td><strong>Total stockholders’ (deficit)/equity</strong></td>
<td>(10,333)</td>
<td>23,740</td>
</tr>
<tr>
<td><strong>TOTAL LIABILITIES &amp; STOCKHOLDERS’ (DEFICIT)/EQUITY</strong></td>
<td>$22,800</td>
<td>$52,020</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these consolidated financial statements.
## ACUSPHERE, INC. AND SUBSIDIARIES
### CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited, in thousands)

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended</th>
<th>Nine Months Ended</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVENUE (1)</strong></td>
<td>$339</td>
<td>$667</td>
</tr>
<tr>
<td><strong>OPERATING EXPENSES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>7,503</td>
<td>11,728</td>
</tr>
<tr>
<td>General and administrative</td>
<td>2,772</td>
<td>3,092</td>
</tr>
<tr>
<td><strong>Total operating expenses</strong></td>
<td>10,275</td>
<td>14,820</td>
</tr>
<tr>
<td>Interest income</td>
<td>45</td>
<td>629</td>
</tr>
<tr>
<td>Other income</td>
<td>55</td>
<td>—</td>
</tr>
<tr>
<td>Loss on extinguishment of debt</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Interest expense</td>
<td>(332)</td>
<td>(490)</td>
</tr>
<tr>
<td>Change in valuation of derivative</td>
<td>(115)</td>
<td>13</td>
</tr>
<tr>
<td><strong>NET LOSS</strong></td>
<td>(10,283)</td>
<td>(14,001)</td>
</tr>
<tr>
<td>Dividends on preferred stock</td>
<td>(390)</td>
<td>(561)</td>
</tr>
<tr>
<td><strong>NET LOSS AVAILABLE TO COMMON STOCKHOLDERS</strong></td>
<td>$ (10,673)</td>
<td>$ (14,562)</td>
</tr>
<tr>
<td><strong>NET LOSS AVAILABLE TO COMMON STOCKHOLDERS PER SHARE</strong> –</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic and diluted</td>
<td>$ (0.23)</td>
<td>$ (0.32)</td>
</tr>
<tr>
<td><strong>WEIGHTED-AVERAGE SHARES OUTSTANDING –</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic and diluted</td>
<td>47,218</td>
<td>46,213</td>
</tr>
</tbody>
</table>

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

(1) Includes related-party amounts of approximately $0.2 million and $0.3 million, respectively, for the three and nine months ended September 30, 2008 (see Note 10).
ACUSPHERE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited, in thousands)

<table>
<thead>
<tr>
<th></th>
<th>Nine Months Ended</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Net loss</td>
<td>$(34,820)</td>
<td>$(41,169)</td>
</tr>
<tr>
<td>Adjustments to reconcile net loss to net cash used in operating activities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stock-based compensation expense</td>
<td>1,429</td>
<td>1,851</td>
</tr>
<tr>
<td>Depreciation and amortization</td>
<td>7,544</td>
<td>7,583</td>
</tr>
<tr>
<td>Loss on disposal of property and equipment</td>
<td>249</td>
<td></td>
</tr>
<tr>
<td>Loss on extinguishment of debt</td>
<td>—</td>
<td>1,146</td>
</tr>
<tr>
<td>Noncash interest expense</td>
<td>553</td>
<td>657</td>
</tr>
<tr>
<td>Noncash rent expense</td>
<td>(144)</td>
<td>8</td>
</tr>
<tr>
<td>Noncash amortization of deferred revenue</td>
<td>(1,860)</td>
<td>(2,000)</td>
</tr>
<tr>
<td>Noncash amortization of fee and warrants to financial advisor</td>
<td>247</td>
<td>168</td>
</tr>
<tr>
<td>Noncash change in valuation of derivative</td>
<td>115</td>
<td>106</td>
</tr>
<tr>
<td>Changes in operating assets and liabilities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deferred revenue</td>
<td>10,750</td>
<td>—</td>
</tr>
<tr>
<td>Other current assets</td>
<td>(538)</td>
<td>(66)</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>(1,112)</td>
<td>(116)</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>741</td>
<td>964</td>
</tr>
<tr>
<td>Net cash used in operating activities</td>
<td>(17,095)</td>
<td>(30,619)</td>
</tr>
<tr>
<td>CASH FLOWS FROM INVESTING ACTIVITIES:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchases of property and equipment</td>
<td>(73)</td>
<td>(769)</td>
</tr>
<tr>
<td>Increase in other assets</td>
<td></td>
<td>24</td>
</tr>
<tr>
<td>Net cash used in investing activities</td>
<td>(73)</td>
<td>(745)</td>
</tr>
<tr>
<td>CASH FLOWS FROM FINANCING ACTIVITIES:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Payments on long-term obligations</td>
<td>(4,832)</td>
<td>(6,897)</td>
</tr>
<tr>
<td>Proceeds from long-term obligations</td>
<td>—</td>
<td>901</td>
</tr>
<tr>
<td>Net proceeds from sale of stock</td>
<td>—</td>
<td>18,698</td>
</tr>
<tr>
<td>Payment of preferred stock dividends</td>
<td>—</td>
<td>(1,714)</td>
</tr>
<tr>
<td>Proceeds from exercise of stock options</td>
<td>—</td>
<td>97</td>
</tr>
<tr>
<td>Proceeds from issuance of common stock from employee stock purchase plan</td>
<td>10</td>
<td>39</td>
</tr>
<tr>
<td>Net cash (used in) provided by financing activities</td>
<td>(4,822)</td>
<td>11,124</td>
</tr>
<tr>
<td>NET DECREASE IN CASH AND CASH EQUIVALENTS</td>
<td>(21,990)</td>
<td>(20,240)</td>
</tr>
<tr>
<td>CASH AND CASH EQUIVALENTS, Beginning of period</td>
<td>26,102</td>
<td>59,750</td>
</tr>
<tr>
<td>CASH AND CASH EQUIVALENTS, End of period</td>
<td>$ 4,112</td>
<td>$ 39,510</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these consolidated financial statements.
ACUSPHERE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Basis of Presentation

The accompanying unaudited consolidated financial statements of Acusphere, Inc. and Subsidiaries (“Acusphere” or the “Company”), have been prepared in accordance with generally accepted accounting principles in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles in the United States of America for complete financial statements. These statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company’s latest audited annual financial statements. Those audited statements are included in our Annual Report on Form 10-K for the year ended December 31, 2007, which has been filed with the SEC.

Acusphere is a specialty pharmaceutical company that develops new drugs and improved formulations of existing drugs using its proprietary microparticle technology. The Company is focused on developing proprietary drugs that can offer significant benefits over existing drugs, including improved safety and efficacy, increased patient compliance, greater ease of use, expanded indications or reduced cost. The Company’s lead product, Imagify™ (perflubutane polymer microspheres for delivery in an injectable suspension, pronounced i-maj’-i-fi, formerly known as AI-700) is a cardiovascular drug for the detection of coronary artery disease, the leading cause of death in the United States. The Company submitted a new drug application (NDA) with the U.S. Food and Drug Administration (FDA) for Imagify on April 28, 2008 which was accepted by the FDA for review on June 30, 2008. With a standard review, under the FDA Prescription Drug User Fee Act (PDUFA), the target action date is 10 months from the submission date, or February 28, 2009. The Company also has demonstrated that its technology has the potential to improve the formulation of hydrophobic drugs and asthma drugs.

The Company is subject to a number of risks similar to those of pre-commercial stage companies, including dependence on key individuals, uncertainty of product development and generation of revenues, dependence on outside sources of capital, risks associated with clinical trials, dependence on third party collaborators for research operations, need for regulatory approval of products, successful protection of intellectual property, and competition with larger, better-capitalized companies.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates or assumptions. The more significant estimates reflected in these financial statements relate to revenue recognition, accrued expenses, embedded derivatives, and valuation of stock-based compensation.

Going Concern Presentation – As of September 30, 2008, the Company had cash and cash equivalents of $4.1 million, current liabilities of $19.6 million and stockholders’ deficit of $10.3 million. During the nine months ended September 30, 2008, the Company incurred a net loss available to common stockholders of $36.3 million. During the nine months ended September 30, 2008, operating activities used approximately $17.1 million of cash. As described in Note 12, the Company obtained $20.0 million in funding on November 3, 2008. However, given the Company’s results from operations, current forecasts, and financial position as of September 30, 2008, the Company will require significant additional funds in order to fund operations through and beyond the second quarter of 2009. These conditions raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying financial statements have been prepared on the basis of a going concern assumption and do not reflect any adjustments that might result from the outcome of this uncertainty.

Management’s Plans – As a result of its limited capital resources, the Company has elected to delay and may continue to elect to delay the funding of certain development activities, including activities related to the commercialization of Imagify, which could harm its financial condition and operating results. The depletion of its resources may make future funding more difficult or expensive to attain. The Company may raise additional funds through public or private sales of equity or from borrowings or from strategic partners. Future capital requirements will depend on many factors, including the scope and progress made in research and development activities and the size and timing of creating expanded manufacturing capabilities. There are no assurances, however, that the Company will obtain additional financing on favorable terms, or at all, or successfully market its products. If the Company is unable to obtain additional financing, it will be forced to cease operations.
2. Revenue Recognition and Deferred Revenue

The Company recognizes revenue from license arrangements in accordance with Staff Accounting Bulletin No. 104, Revenue Recognition (“SAB 104”) and Financial Accounting Standards Board (“FASB”) Emerging Issue Task Force Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables (“EITF 00-21”). The Company recognizes revenue from license payments not tied to achieving a specific performance milestone ratably over the period over which the Company is obligated to perform services. The period over which the Company is obligated to perform services is estimated based on available facts and circumstances. The Company periodically evaluates the assumptions underlying these estimates; significant changes in these assumptions could result in an adjustment to the period over which the revenue is recognized. The Company recognizes revenue from performance payments, when such performance is substantially in the Company’s control and when the Company believes that completion of such performance is reasonably probable, ratably over the period over which the Company estimates that it will perform such performance obligations. Substantive at-risk milestone payments, which are based on achieving a specific performance milestone when performance of such milestone is contingent on performance by others or for which achievement can not be reasonably estimated or assured, are recognized as revenue when the milestone is achieved and the related payment is due, provided that there is no substantial future service obligation associated with the milestone. Revenue in connection with license arrangements is recognized over the term of the arrangement and is limited to payments collected or due and reasonably assured of collection. In circumstances where the arrangement includes a refund provision, the Company defers revenue recognition until the refund condition is no longer applicable unless, in the Company’s judgment, the refund circumstances are within its operating control and unlikely to occur. Payments received in advance of being recognized as revenue are deferred. Contract amounts which are not due until the customer accepts or verifies the research results are not recognized as revenue until customer acceptance, assuming collectability is reasonably assured.

On March 28, 2008, the Company entered into a license agreement (the “Cephalon License”) with Cephalon, Inc. (“Cephalon”), a related party (See Note 10), providing Cephalon with an exclusive, worldwide license to the Company’s Hydrophobic Drug Delivery System (HDDS) for oncology applications, along with the rights to AI-850, the Company’s formulation of paclitaxel, in exchange for a cash payment of $10.0 million, paid upon the execution of the agreement. The term of the agreement extends until expiration of the last of the patents licensed under the agreement. During the term of the license the Company is obligated to support Cephalon activities in connection with AI-850. This support includes allowing access to Acusphere personnel for discussions relating to regulatory, scientific and medical technology and allow access to any records that may be required in connection with any regulatory filings or submissions. On September 2, 2008, the Company entered into a letter agreement amending the Cephalon License. The amendment did not modify the accounting treatment with respect to the Cephalon License. The Company has recorded this payment in deferred revenue at September 30, 2008, and is recognizing it as income ratably over the remaining estimated useful life of the patents, or approximately 13 years. The Company began recognizing revenue under the Cephalon License in the second quarter of 2008.

In July 2004, the Company entered into a collaboration, license and supply agreement with Nycomed Danmark APS (“Nycomed”) in which the Company granted Nycomed rights to develop and market Imagify in Europe. As of September 30, 2008, Nycomed has paid $12.0 million in license fees for the Company’s research and development efforts, which is being recognized ratably in revenue over the development period. Estimation of this development period involves the evaluation of many assumptions and uncertainties inherent in the performance of a long-term development project. The Company regularly evaluates these assumptions and uncertainties and the estimated development recognition period may change if facts and circumstances change. There was no change in the change in the amortization period during the year ended December 31, 2007. During the third quarter of 2008, management reevaluated the assumptions underlying the development term and revised the estimated development period from 54 months to 66 months. The remaining $2.7 million of the $12.0 million in development payments already received, but yet to be recognized as revenue, is included in deferred revenue at September 30, 2008 and will be recognized over the remaining estimated development period.

In October 2005 and February 2006, the Company and Nycomed amended the collaboration agreement to accelerate $2.0 million in milestone payments in order to fund certain activities associated with brand development and qualification of a commercial manufacturing facility. The $2.0 million in payments received pursuant to these amendments were considered advances against a future milestone payment for a European regulatory filing, or Marketing Authorization Application (“MAA”). In September 2008, the arrangement with Nycomed was amended. This amendment removed a contingency associated with the $2.0 million of payments. As a result the $2.0 million has been included with the aforementioned $12 million and is being recognized over the 66 month development period utilizing the cumulative catch-up methodology. Approximately $0.5 million of the $2.0 million in development payments already received, but yet to be recognized as revenue, is included in deferred revenue at September 30, 2008 and will be recognized over the remaining estimated development period.
On June 26, 2008, the Company executed the Third Amendment (the “Third Amendment”) to the Collaboration, License and Supply Agreement dated July 6, 2004 with Nycomed, as amended, for the European development and marketing rights to Acusphere’s product candidate AI-700 or Imagify™ (the “Product”). Pursuant to the Third Amendment, Nycomed shall reimburse the Company for expenses arising from and after June 1, 2008 and related to the Company’s qualification of its commercial manufacturing facility in Tewksbury, Massachusetts. Such amounts shall not, in the aggregate, exceed $750,000 and are payable by Nycomed upon receipt of monthly invoices. The Third Amendment further provides that $750,000 shall be credited against Nycomed’s initial purchases of the Product so that Nycomed shall only pay for Products delivered after such $750,000 has been fully credited. The Company has included the $750,000 in long-term deferred revenue.

3. Stock-based Compensation

Accounting for Stock-Based Compensation Plans

Effective January 1, 2006, the Company adopted SFAS No. 123R, Share-Based Compensation (“SFAS 123R”) using the modified prospective method, which results in the provisions of SFAS 123R being applied to the consolidated financial statements on a going-forward basis. SFAS 123R requires companies to recognize stock-based compensation awards granted to its employees as compensation expense on a fair value method. Under the fair value recognition provisions of SFAS 123R, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the service period, which generally represents the vesting period. The grant date fair value of stock options is calculated using the Black-Scholes option-pricing model and the grant date fair value of restricted stock is based on intrinsic value. The expense recognized over the service period is required to include an estimate of the awards that will be forfeited.

All stock-based awards to non-employees are accounted for at their fair value in accordance with SFAS 123R and Emerging Issues Task Force No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. Under this method, the equity-based instrument was valued at either the fair value of the consideration received or the equity instrument issued on the date of grant. The resulting compensation cost was recognized and charged to operations over the service period, which was usually the vesting period.

Stock compensation expense under SFAS 123R for the three and nine months ended September 30, 2008 and 2007 is as follows (in millions):

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended September 30,</th>
<th>Nine Months Ended September 30,</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research &amp; development</td>
<td>$0.2</td>
<td>$0.3</td>
</tr>
<tr>
<td>General &amp; administrative</td>
<td>0.2</td>
<td>0.3</td>
</tr>
<tr>
<td>Total</td>
<td>$0.4</td>
<td>$0.6</td>
</tr>
</tbody>
</table>

In accordance with SFAS 123R, the Company will report any excess tax benefits from the exercise of non-qualified stock options as financing cash flows. There were no excess tax benefits recorded from the exercise of non-qualified stock options for the nine months ended September 30, 2008 and 2007.

For purposes of recording stock option-based compensation expense, the fair values of each stock option granted under the Company’s stock option plan were estimated as of the date of grant using the Black-Scholes option-pricing model. The weighted average fair value of all stock option grants issued for the three months ended September 30, 2008 and 2007 were $0.36 and $0.81, respectively, and for the nine months ended September 30, 2008 and 2007 were $0.33, and $1.27, respectively.

The fair values of all stock option grants issued were determined using the following weighted average assumptions:

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended September 30,</th>
<th>Nine Months Ended September 30,</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk-free interest rate</td>
<td>3.45%</td>
<td>4.31%</td>
</tr>
<tr>
<td>Expected volatility of underlying stock</td>
<td>76.4%</td>
<td>54.71%</td>
</tr>
<tr>
<td>Expected life of option grants (years)</td>
<td>5.0</td>
<td>5.0</td>
</tr>
<tr>
<td>Expected dividends</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
The fair values of options granted during six-month period ended August 31, 2008 and 2007 under the Company’s Purchase Plan were calculated using the following weighted-average assumptions:

<table>
<thead>
<tr>
<th></th>
<th>2008</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk-free interest rate</td>
<td>1.97%</td>
<td>4.21%</td>
</tr>
<tr>
<td>Expected volatility of underlying stock</td>
<td>75.9%</td>
<td>54.40%</td>
</tr>
<tr>
<td>Expected life of option (years)</td>
<td>0.5</td>
<td>0.5</td>
</tr>
</tbody>
</table>

**Stock Option Activity**

During the three months ended September 30, 2008, the Company granted stock options to existing employees, as part of the Company’s performance review process and new employees and directors. All such options were granted with exercise prices equal to the current market value of the underlying common stock on the date of grant.

On August 31, 2008, the company issued 12,927 shares of its common stock under the Purchase Plan at $0.38 per share, reflecting 85% of the closing stock price.

Stock option activity for the nine months ended September 30, 2008:

<table>
<thead>
<tr>
<th></th>
<th>Number of Shares</th>
<th>Exercise Price Per Share</th>
<th>Weighted Average Exercise Price Per Share</th>
<th>Grant Date Fair Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>For the three months ended September 30, 2008:</td>
<td>685,903</td>
<td>$0.56</td>
<td>$0.56</td>
<td>$245,896</td>
</tr>
</tbody>
</table>

As of September 30, 2008, there was $1.8 million of total expected unrecognized compensation costs related to unvested stock options under the Company’s stock-based plans. That cost is expected to be recognized over a weighted-average period of 2.9 years.

**4. Net Loss Per Common Share**

Basic and diluted net loss per common share is calculated by dividing the net loss available to common stockholders by the weighted-average number of unrestricted common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share, since the effects of potentially dilutive securities are anti-dilutive for all periods presented. As of September 30, 2008 and 2007, anti-dilutive securities, which consist of convertible exchangeable preferred stock, stock options, warrants, and restricted common stock that are not included in the diluted net loss per share calculation aggregated 18,973,154 and 19,435,320 shares, respectively.
5. Balance Sheet Data

( in thousands)

<table>
<thead>
<tr>
<th>Other assets consist of the following:</th>
<th>September 30, 2008</th>
<th>December 31, 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deposits</td>
<td>$1,139</td>
<td>$1,126</td>
</tr>
<tr>
<td>Other assets</td>
<td>$195</td>
<td>$285</td>
</tr>
<tr>
<td><strong>Total Other assets</strong></td>
<td><strong>$1,334</strong></td>
<td><strong>$1,411</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Accrued expenses consist of the following:</th>
<th>September 30, 2008</th>
<th>December 31, 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accrued contract services</td>
<td>$826</td>
<td>$1,404</td>
</tr>
<tr>
<td>Accrued vacation (1)</td>
<td>67</td>
<td>517</td>
</tr>
<tr>
<td>Accrued bonus (2)</td>
<td>1,028</td>
<td>129</td>
</tr>
<tr>
<td>Other accrued expenses (3)</td>
<td>2,483</td>
<td>1,546</td>
</tr>
<tr>
<td><strong>Total accrued expenses</strong></td>
<td><strong>$4,404</strong></td>
<td><strong>$3,596</strong></td>
</tr>
</tbody>
</table>

Note (1) – The Company’s current vacation policy allows employees to carry over unused vacation time as of December 31 of each year, up to a maximum of two weeks. However, several employees who joined the Company prior to the institution of this vacation policy had accumulated more than two weeks vacation at December 31, 2007. These employees had been allowed to carry this excess vacation accrual forward each year. In April 2008 approximately $0.7 million of this accumulated vacation liability to employees was paid in a lump sum payment.

Note (2) – On July 28, 2008, the Company announced that, pursuant to the Senior Management Compensation Plan approved by the Compensation Committee of the Company’s Board of Directors on July 25, 2008, all senior managers at the Vice President level and above (“Management”) took salary reductions of 10% or more, to further decrease operating costs while the Company awaits Food and Drug Administration (“FDA”) review of its New Drug Application (“NDA”) for Imagify™ (Perflubutane Polymer Microspheres for Injectable Suspension). The salary reductions described were effective on August 1, 2008. In connection with such reductions and pursuant to the Senior Management Compensation Plan, on July 25, 2008 the Compensation Committee and the Board of Directors granted common stock option awards to each member of Management pursuant to the Company’s 2005 Stock Option and Incentive Plan. The options vest 100% upon completion of the first debt or equity financing in excess of $10 million by the Company after the Prescription Drug User Fee Act (“PDUFA”) date, currently expected to be February 28, 2009, for Imagify or upon an acquisition of the Company (a “Qualified Financing”). Each member of Management who is still employed by the Company upon the completion of a Qualified Financing will also receive a cash bonus equal to the total amount of pre-reduction base salary forgone as a result of the Management base salary reduction; provided that members of Management may also elect to take additional base salary reductions in exchange for a larger cash retention bonus and option grant. For reductions of 20%, for every dollar of pay cut there will be two dollars of cash retention bonus and twice the level of option grants.

In September 2008, the Board approved a supplemental bonus program for full time employees employed by the Company as of September 15, 2008. Employees who carry the title of Vice President or above are not eligible for this program. The amount of the bonus will be 25% of such employee’s base salary at the time of the payment. The bonus is contingent upon such employees remaining an employee of the Company through the FDA’s complete response letter to the Company’s NDA for Imagify which is expected on or about the PDUFA action date of February 28, 2009. In addition, the bonus is further contingent upon the Board’s determination that the Company completed a financing to provide sufficient funding to make the proposed bonus payment. If the contingencies are met and all employees eligible remained through that date, the bonus would amount to approximately $1.3 million.

The Company began ratably accruing for these bonuses in September 2008 and the accrued amount at September 30, 2008 was approximately $300,000.

Note (3) – Includes an $0.6 million payable under an intellectual property license agreement with Bracco. On July 29, 2008, the Company entered into an amendment (the “Amendment”) to the Bracco International BV patent license agreement. See “Footnote 6. Intellectual Property”.

6. Intellectual Property

The Company expenses intellectual property costs incurred in obtaining license right and patent rights to technology or products for which technological feasibility has not been commercially demonstrated and no alternative future use has been shown to exist. No amount has been capitalized by the Company relating to the costs of intellectual property developed or acquired by the Company.

On June 1, 2006, the Company entered into an agreement to license on a non-exclusive basis various ultrasound-related intellectual property from GE Healthcare (“GE”), a division of General Electric Company. In consideration of the non-exclusive license of these patents, the Company agreed to pay GE $10.0 million prior to commercial approval of Imagify, of which $5.0 million was paid in
On June 1, 2006, the Company entered into an agreement to license on a non-exclusive basis various ultrasound-related intellectual property from Bracco International BV (“Bracco”). The agreement provides the Company with use of Bracco’s ultrasound-related patents and patent applications in combination with the Company’s lead product candidate Imagify in the field of ultrasound diagnostic imaging. The term of the agreement extends until expiration of the last of the patents licensed under the agreement. In consideration for the non-exclusive license of these patents, the Company agreed to pay Bracco up to a total of Euros 3.0 million, of which Euros 0.5 million (approximately $0.6 million) was paid in June 2006. On July 29, 2008, the Company entered into an amendment to the Bracco patent license agreement. Under the Bracco patent license agreement, the Company was obligated to make a payment of Euros 500,000 (approximately $0.8 million) to Bracco within five business days after the acceptance by the FDA of a new drug application filing package for Imagify. The FDA accepted the Company’s application on June 30, 2008, making such payment to Bracco due on July 8, 2008. The Amendment reduces the amount of the payment due on July 8, 2008 to Euros 100,000 (approximately $0.2 million), and provides that an additional payment of Euros 400,000 (approximately $0.6 million) will be due on the first anniversary of such acceptance by the FDA, or June 30, 2009. The Amendment further provides that the Company grants Bracco a perpetual non-exclusive and royalty-free right and license within the field of ultrasound diagnostic imaging to use and exploit any intellectual property that the Company has developed or may develop after June 1, 2006 which relates to, or to the use or performance of, the patents licensed by Bracco under the Agreement. The Company has made the payment of Euro 100,000 (approximately $0.2 million) in August 2008 and the remaining payment of Euros 400,000 (approximately $0.6 million) that is due on the first anniversary of such acceptance by the FDA, or June 30, 2009 is classified in current liabilities as of September 30, 2008. An additional Euros 2.0 million is payable upon the Company’s achievement of certain defined regulatory milestones. The Company also agreed to pay a royalty on future Imagify revenue, up to a maximum royalty amount of Euros 10.0 million, less a portion of the above-referenced milestone payments. These other obligations have not been recorded at this time since they are contingent upon the outcome of future events.

On May 11, 2005, the Company entered into a Patent Transfer Agreement with Bayer Schering Pharma AG (“Schering”) pursuant to which the Company acquired rights, title and interest in certain ultrasound-related patents from Schering. In consideration of the transfer and assignment of these patents, the Company agreed to pay Schering a total of $7.0 million of which $1.0 million was paid in May 2005, $3.0 million was paid in May 2006, and $3.0 million was due in May 2007. Effective April 27, 2007 the Company entered into an amendment (the “First BSP Amendment”) to the Schering patent transfer agreement. Pursuant to the First BSP Amendment $1.5 million was paid in May 2007. On May 15, 2008, the Company entered into a second amendment (the “Second BSP Amendment”) to the Schering patent transfer agreement. Under the First BSP Amendment, the Company was due to make a payment of $1.0 million to Schering on or before fifteen days after May 11, 2008 and a payment of another $1.0 million to Schering on or before fifteen days after May 11, 2009. The Second BSP Amendment provides that, in lieu of these payments, the Company shall make a series of payments due as follows: $200,000 on or before fifteen days following execution of the Second BSP Amendment and $1.8 million on or before fifteen days after May 11, 2009. The $200,000 payment was paid in May 2008 and the current carrying value of the remaining $1.8 million has been included in the current portion of long-term obligations at September 30, 2008.

7. Long-term Obligations

The carrying value of long-term obligations is as follows (in thousands):
### Capital Lease Obligations

The Company leases capital equipment through Banc of America Leasing Corporation. The remaining monthly payments range from $460 to $1,019 with maturities through June 2010. Interest rates for the above leases range from 7.3% to 9.4%. Acusphere does not have any additional borrowing availability under these lease arrangements as of September 30, 2008. At September 30, 2008 and December 31, 2007, the cost and net carrying value of equipment under capital leases amounted to approximately $47,000 and $67,000, respectively.

### Notes Payable

**Equipment Promissory Notes**— In 2004 and 2005, the Company borrowed an aggregate of $10.5 million under an equipment financing line with GE Capital Corporation. In January 2006, the line was amended and the availability was increased by an additional $3.5 million and was extended through May 2007. During the year ended December 31, 2007, the Company borrowed approximately $0.9 million, no additional amounts may be borrowed under this line. Borrowings are collateralized by equipment and other capital purchases made with the proceeds from these notes, with repayment due in monthly installments over 36 to 48 months, depending on the nature of the equipment financed, with the last such repayment scheduled for December 2010. Interest rates on these borrowings were fixed at the time of each borrowing and range from 8.7% to 10.7%. The loans under this line are subject to acceleration upon certain events of default, including but not limited to: i) the failure to make timely payments of principal and interest, ii) a default on other material obligations, or iii) a material adverse change in the financial condition of the borrower. As of September 30, 2008, net of repayments, the Company had $2.5 million outstanding under the line.

In 2005 the Company borrowed an aggregate of $7.0 million under an equipment financing line with Oxford Finance Corporation. As of September 30, 2008, net of repayments, the Company had $2.0 million outstanding under the line. Borrowings are collateralized by the equipment financed, with repayment due in monthly installments over 36 to 48 months, with the last such repayment scheduled for March 2010. Interest rates on these borrowings were fixed at the time of each borrowing and range from 10.3% to 10.9%. The loans under this line are subject to acceleration upon certain events of default, including but not limited to the failure to make timely payments of principal and interest, a default on other material obligations, or a material adverse change in the financial condition of the borrower. No additional amount may be borrowed under this line.

**Facility Loan Agreement**— In March 2005 the Company borrowed $2.0 million under a loan agreement with MassDevelopment to help finance certain tenant improvements to its commercial manufacturing facility in Tewksbury, Massachusetts. The loan is secured by certain improvements made at the facility, interest accrues at 5.0% per annum with retroactive adjustments to 9.0% in the event the Company achieves positive operating cash flow, as defined in the agreement, prior to repayment of the loan. Accrued principal and interest are being repaid over a 10 year term. The loan is subject to acceleration upon certain customary events of default, including failure to timely pay principal and interest. Acusphere began making payments on this loan in May 2007 and as of September 30, 2008, has approximately $1.9 million outstanding under the loan.

The retroactive interest rate adjustment feature of the loan agreement was deemed to be an embedded derivative instrument requiring separate accounting under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and was initially valued at $62,000. The derivative asset is being amortized as interest expense over a term beginning with the loan agreement effective date and ending with the currently expected payment date of the retroactive interest. The fair value of the derivative liability is re-measured at each reporting period, with any change in value charged or credited to interest expense. There was no change in the estimated fair value of the derivative liability at September 30, 2008.

FASB Statement No. 157 *Fair Value Measurements* (“SFAS No. 157”) establishes a three-tier fair value hierarchy, which classifies the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs for which little or no market data exists, therefore requiring an entity to develop its own assumptions. The fair value of the derivative liability is determined utilizing a model which is classified as Level 3 under SFAS No. 157.

### Amounts Due Under Intellectual Property Agreements

Under the Company’s amended patent transfer agreement with Schering, a $1.8 million payment is due in May 2009. Under the Company’s amended license agreement with GE, the Company is scheduled to make a $4.6 million payment (plus interest) in October.
dilution adjustment. The Company has reserved approximately 3.5 million shares of common stock for issuance upon such conversion. The Company may elect to automatically convert some or all of the Preferred Stock into shares of common stock if the closing price of the Company’s common stock has exceeded $10.30 per share (150% of the conversion price) for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion. Prior to March 1, 2009, if the Company elects to automatically convert, or if any holder elects to voluntarily convert, the Preferred Stock, the Company will also make an additional payment (“Make-Whole” payment) equal to the aggregate amount of dividends that would have been payable on the Preferred Stock so converted from the original date of issuance through and including March 1, 2009, less any dividends already paid on the Preferred Stock. This additional payment is payable by the Company, at its option, in cash, in additional shares of its common stock, or in a combination of cash and shares of common stock. The Company has reserved a maximum of approximately 0.3 million shares of common stock for issuance under this Make-Whole provision.

In August 2008, one stockholder voluntarily converted 170,000 shares of Preferred Stock into 1,239,066 shares of the Company’s common stock. In connection with the conversion, the Company issued an additional 115,682 shares of the Company’s common stock in satisfaction of the required Make-Whole payment.
In February 2008, one stockholder voluntarily converted 40,000 shares of Preferred Stock into 291,545 shares of the Company’s common stock. In connection with the conversion, the Company issued an additional 27,219 shares of the Company’s common stock in satisfaction of the required Make-Whole payment.

From February 2005 through September 30, 2008, 420,000 shares of Preferred Stock have been voluntarily converted into 3,061,223 shares of the Company’s common stock. In connection with such conversions, the Company issued an additional 490,504 shares of the Company’s common stock in satisfaction of the required Make-Whole payment. The fair value of these Make-Whole payments was approximately $1.8 million, which was charged against the derivative liability.

In accordance with SFAS No. 133, the Company is required to separate and account for as an embedded derivative, the dividend make-whole payment feature of the Preferred Stock offering. As an embedded derivative instrument, the dividend make-whole payment feature must be measured at fair value and reflected as a liability. Changes in the fair value of the outstanding portion of the derivative are recognized in earnings as unrealized gain or loss on derivative in the statement of operations. The Company determined the fair value of the dividend make-whole payment feature to be $3.1 million at February 24, 2005 (the commitment date). This amount was allocated from the proceeds of the Preferred Stock to the derivative liability. At September 30, 2008, the derivative liability was valued at $64,000 and at December 31, 2007, the fair value was $13,000. The fair value of the derivative liability is determined utilizing a model which is classified as Level 3 under SFAS No. 157.

The Company may elect to redeem the Preferred Stock at declining redemption prices on or after March 6, 2009.

The Preferred Stock is exchangeable, in whole but not in part, at the option of the Company on any dividend payment date for the Company’s 6.5% convertible subordinated debentures (“Debentures”) at the rate of $50 principal amount of Debentures for each share of Preferred Stock. The Debentures, if issued, will mature 25 years after the Exchange Date and have terms substantially similar to those of the Preferred Stock.

The Preferred Stock has no maturity date and no voting rights prior to conversion into common stock, except under limited circumstances.

**Common Stock**

As of September 30, 2008, there were 98.5 million shares of common stock authorized, 48.1 million shares of common stock outstanding and 22.8 million shares of common stock reserved for issuances, representing 3.5 million shares reserved for issuance in connection with outstanding convertible exchangeable preferred stock, 0.3 million shares reserved for issuance in connection with the make-whole payments provisions of the outstanding convertible exchangeable preferred stock, 8.8 million shares reserved for issuance in connection with outstanding common stock warrants, 6.7 million shares reserved for issuance in connection with outstanding stock options, 3.3 million shares reserved for issuance, in aggregate, in connection with shares available for future stock or option grants under the 2003 Stock Option Plan and Amended 2005 Stock Option Plan, and 0.2 million shares reserved for issuance under the Employee Stock Purchase Plan.

### 9. Common Stock Warrants

As of September 30, 2008, warrants to purchase shares of the Company’s common stock, the origination of which were derived in connection with debt and lease financing transactions, the collaborative agreement with Nycomed and the April 2006, December 2006 and June 2007 common stock offerings, were outstanding for an aggregate of 8,776,432 shares of common stock at an effective weighted average price of $4.39 per share as follows:

<table>
<thead>
<tr>
<th>Number of Shares</th>
<th>Exercise Price Per Share</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>16,212</td>
<td>19.80</td>
<td>October 16, 2008</td>
</tr>
<tr>
<td>14,934</td>
<td>19.80</td>
<td>October 19, 2008</td>
</tr>
<tr>
<td>114,895</td>
<td>8.50</td>
<td>October 20, 2008</td>
</tr>
<tr>
<td>55,732</td>
<td>6.28</td>
<td>November 30, 2009</td>
</tr>
<tr>
<td>2,688</td>
<td>19.80</td>
<td>January 5, 2010</td>
</tr>
</tbody>
</table>
10. Related Party Transaction

On March 28, 2008, the Company entered into a license agreement with Cephalon providing Cephalon with an exclusive, worldwide license to the Company’s formulation of paclitaxel, in exchange for a cash payment of $10.0 million, paid upon the execution of the agreement. The term of the agreement extends until expiration of the last of the patents licensed under the agreement. The Chairman, founder and CEO of Cephalon is also the current Presiding Director of the Board of Directors of the Company. Martyn Greenacre is a member of the Board of Directors of both the Company and Cephalon. As of September 30, 2008, approximately $0.8 million is included in current portion of deferred revenue and approximately $8.9 million is included in the long-term deferred revenue. In addition, the Company recognized approximately $0.2 million and $0.3 million, respectively, for the three and nine months ended September 30, 2008 of revenue associated with this agreement.

11. New Accounting Pronouncements

In September 2006, the FASB issued SFAS (SFAS) No. 157, *Fair Value Measurements*, which is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The purpose of FAS No.157 is to clarify and set forth consistent rules for defining fair value, establishing a framework for measuring fair value in generally accepted accounting principles and expanding disclosures about fair value measurements. SFAS No.157 applies under other accounting pronouncements that require or permit fair value measurements where those accounting pronouncements have determined that fair value is the relevant measurement attribute. SFAS No. 157 does not require any new fair value measurements, but for some entities the application of SFAS No. 157 could change current practice. Except as described below, we have adopted SFAS No. 157 on January 1, 2008. The adoption of SFAS No. 157 did not have a material impact on the Company’s financial statements or disclosures.

In February 2008, FASB issued FASB FSP FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2). FSP 157-2 will provide a one-year deferral of the effective date of SFAS No. 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in financial statements at fair value at least annually. For non-financial assets and non-financial liabilities subject to the deferral, SFAS No. 157 will be effective in fiscal years beginning after November 15, 2008 and in interim periods within those fiscal years. The Company is currently evaluating the impact that applying FAS No. 157 to nonfinancial assets and liabilities will have on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which is effective as of the beginning of an entity’s first fiscal year beginning after November 15, 2007. This statement allows the measurement at fair value of financial instruments and certain other items that are currently not required to be measured at fair value. The objective of SFAS No. 159 is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. The fair value option established by this statement permits the measurement of eligible items at fair value at specified election dates, with unrealized gains and losses on the items for which the fair value option has been elected reported in earnings at each subsequent reporting date. SFAS No. 159 was effective for the Company in the first quarter of 2008. The adoption of SFAS No. 159 did not have an impact on the Company’s financial statements or condition as they did not elect to use fair value measurements on any assets or liabilities under this statement and have not subsequently elected to carry any assets or liabilities at fair value.

In June 2007, the Emerging Issues Task Force issued EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*, which is effective as of the beginning of an entity’s first fiscal year beginning after December 15, 2007. This abstract discusses the treatment of the nonrefundable portion of advance payments made pursuant to an executory contractual arrangement for future research and development activities. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. The Company adopted this statement as of January 1, 2008 and concluded it has no effect on its consolidated financial statements.
In March 2008, the FASB issued SFAS No. 161, an amendment of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, which is effective as of the beginning of an entity’s first fiscal year beginning after November 15, 2008. This Statement changes the disclosure requirements for derivative instruments and hedging activities, requiring enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under Statement 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity’s financial position, financial performance, and cash flows. The Company is assessing the impact, if any, of this pronouncement on its consolidated financial statements.

12. Subsequent Events

On November 3, 2008 the Company closed a transaction with Cephalon to provide $20 million in upfront funding to the Company. Cephalon purchased a $15 million senior secured convertible note (the “Cephalon Note”) and paid a $5 million upfront fee for an exclusive worldwide license to AI-525, a preclinical-stage injectable formulation of celecoxib using the Company’s proprietary Hydrophobic Drug Delivery System (HDDS™) technology (the “Celecoxib License”). The terms of the Celecoxib License also include a milestone payment of $15 million upon the receipt from the US Food and Drug Administration (“FDA”) of final approval of the first New Drug Application or NDA with respect to celecoxib for any indication, and certain royalty payments based on future sales by Cephalon of celecoxib. The transaction with Cephalon described in this Note 12 shall be referred to collectively as the “Cephalon Transaction”. The Chairman, founder and CEO of Cephalon is also the current Presiding Director of the Board of Directors of the Company. Martyn Greenacre is a member of the Board of Directors of both the Company and Cephalon.

The Cephalon Note includes an annual interest rate of 8.0% payable annually over three years in cash or shares of the Company’s common stock at the Company’s election. The Cephalon Note is secured by certain assets of the Company, including all of the Company’s intellectual property, pursuant to the terms of a Pledge and Security Agreement with Cephalon. The Cephalon Note is subject to acceleration and an increased interest rate of 15% upon the happening of customary events of default, including the failure to make timely payments of principal and interest.

The Cephalon Note is convertible at Cephalon’s option any time prior to November 3, 2009 into one of the following: (i) the greater of (A) the number of shares of the Company’s common stock equal to $15 million divided by 90% of $0.486 (subject to certain adjustments as provided in the Cephalon Note) or (B) the number of shares of the Company’s common stock equal to 51% of the Company’s outstanding common stock on a fully-diluted basis as calculated as set forth in the Cephalon Note on the date of conversion of the Cephalon Note, (ii) the right to enter into an exclusive license to all intellectual property rights of the Company relating to Imagify™ (Perflubutane Polymer Microspheres) for Injectable Suspension (the “Imagify License”) to use, distribute and sell Imagify for all current and future indications including coronary heart disease, in a worldwide territory, excluding those European countries for which Nycomed Danmark ApS has rights pursuant to that certain Collaboration, License and Supply Agreement dated as of July 6, 2004, as amended, or (iii) the satisfaction of Cephalon’s obligation to pay the Company the $15 million milestone payment for approval of the injectable formulation of celecoxib by the FDA for any indication pursuant to the Celecoxib License. In connection with the possible conversion of the Cephalon Note into shares of the Company’s common stock, the Company has also entered into a registration rights agreement with Cephalon pursuant to which the Company has agreed to register for resale shares of the Company’s common stock held by Cephalon.

If Cephalon elects to convert the Cephalon Note into the right to enter into the Imagify License, the Company is entitled to a $40 million regulatory milestone payment upon final FDA approval of the first NDA for Imagify for the detection of coronary artery disease and certain royalty payments based on future sales by Cephalon of Imagify. The term of the Imagify License would extend until the expiration of the last of the patent rights licensed under such agreement.

The Cephalon Note was issued pursuant to a Note Purchase Agreement between the Company and Cephalon (the “Note Purchase Agreement”), which provides for customary representations and warranties and covenants regarding the conduct of the Company’s business for so long as the Cephalon Note remains outstanding or Cephalon holds at least 25% or more of the Company’s outstanding voting securities (the “Restricted Period”). The Company has also granted Cephalon preemptive rights during the Restricted Period. In addition, from and after the conversion of the Cephalon Note and for so long as Cephalon holds at least 25% or more of the Company’s outstanding voting securities, Cephalon will have the right to designate that number of directors to the Company’s Board of Directors that is proportional to its equity interest, provided that any future transaction between the Company and Cephalon must be approved by a committee of directors consisting entirely of directors that are independent of Cephalon.

In connection with Cephalon Transaction, and pursuant to the stockholder approval received at the Company’s annual meeting of stockholders on June 5, 2008, the Company filed on October 31, 2008 an amendment to its certificate of incorporation with the
Secretary of State of the State of Delaware increasing the authorized number of shares of its common stock from 98.5 million to 250 million shares.

In October 2008, two stockholders voluntarily converted, in the aggregate, 170,000 shares of Preferred Stock into 1,239,066 shares of the Company’s common stock. In connection with the conversion, the Company issued an additional 115,682 shares of the Company’s common stock in satisfaction of the required Make-Whole payment.
ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Statements contained herein, including without limitation, “Management’s Discussion and Analysis of Financial Condition and Results of Operation,” contains certain projections, estimates and other forward-looking statements. “Forward-looking statements,” as that term is defined in the Private Securities Litigation Reform Act of 1995, are not historical facts and involve a number of risks and uncertainties. Words herein such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “intends,” “potential,” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Forward-looking statements include, but are not limited to: our capital requirements and our needs for additional financing; the timing and level of future expenses, revenues and profitability; the timing of these development programs, in particular our estimates of the timing of an MAA for Imagify; the timing and likelihood of regulatory approval of an NDA and MAA for Imagify; the level of clinical and commercial interest in Imagify; the required size and make-up of a sales force to effectively launch Imagify; our development of other product candidates; our ability to qualify a commercial manufacturing facility for Imagify; our estimates of the size of the potential markets for our product candidates; our selection and licensing of product candidates; our ability to attract and retain collaborators with acceptable development, regulatory and commercialization expertise; the benefits to be derived from corporate collaborations, license agreements and other collaborative efforts, including those relating to the development and commercialization of our product candidates; sources of revenues and anticipated revenues, including contributions from corporate collaborations, license agreements and other collaborative efforts for the development and commercialization of products; our ability to create an effective direct sales and marketing infrastructure for products we elect to market and sell directly; the rate and degree of market acceptance of our product candidates; the timing and amount of reimbursement for our product candidates; the success and timing of other competing therapies that are or may become available; and the manufacturing capacity for our product candidates.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements. Any forward-looking statement should be considered in light of factors discussed in Part II, Item 1A “Risk Factors” and elsewhere in this report. We caution readers not to place undue reliance on any such forward-looking statement, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the Securities and Exchange Commission, to publicly update or revise any such statements to reflect any change in company expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

The following discussion should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Form 10-Q and with our Annual Report on Form 10-K.

Overview

We are a specialty pharmaceutical company that develops new drugs and improved formulations of existing drugs using our proprietary porous microparticle technology. We are focused on developing proprietary drugs that can offer significant benefits such as improved safety and efficacy, increased patient compliance, greater ease of use, expanded indications or reduced cost. Our lead product candidate, Imagify™ (perfluorbutane polymer microspheres), is a cardiovascular drug for the detection of coronary artery disease, the leading cause of death in the United States. We submitted our new drug application (“NDA”) for Imagify in April 2008 and the NDA was accepted by the FDA for review on June 30, 2008. The FDA acceptance of the NDA submission indicates that the application is sufficiently complete to permit a substantive review and meets the threshold for filing. With a standard review, under the FDA Prescription Drug User Fee Act (PDUFA), the target action date is 10 months from the submission date, or February 28, 2009. The FDA has published a Federal Register Notice on the FDA website of a planned public meeting of the Cardiovascular and Renal Drugs Advisory Committee on December 10, 2008, the agenda of which includes a review of Imagify. In Europe, we have entered into a collaboration agreement with Nycomed for the marketing and sale of Imagify. Nycomed is responsible for the filing of a Marketing Authorization Application (“MAA”) for Imagify in Europe. Nycomed’s filing of the European MAA is now planned for 2009. In addition to our progress with Imagify, we have demonstrated that our technology can improve the formulation of hydrophobic drugs and inhaled asthma drugs.

We believe that Imagify perfusion ultrasound has the potential to significantly reduce the time, cost and resources needed in the assessment of myocardial perfusion, compared to nuclear stress testing, without subjecting patients to radiation. Myocardial perfusion is blood flow to the heart muscle, a sensitive marker for coronary artery disease. There is no ultrasound imaging agent currently
We developed Imagify and our other product candidates using our proprietary technology which enables us to control the size and porosity of particles, including nanoparticles and microparticles, in a versatile manner, so we can customize the particles to address the delivery needs of a variety of drugs. We are focused on creating porous microparticles that are smaller than red blood cells. Some of these microparticles are nanoparticles which are smaller than one micron. Small microparticles are important for delivering drugs intravenously so that they can pass through the body’s smallest blood vessels, for increasing the surface area of a drug so that the drug will dissolve more rapidly, and for delivering drugs to the lung via inhalation. Porosity is important for entrapping gases in microparticles, for controlling the release rate of the drug from a microparticle, and for targeting inhaled drugs to specific regions of the lung.

There were three different ultrasound readers in each of RAMP-1 and RAMP-2 (six readers in total). All three readers demonstrated non-inferiority to nuclear stress with respect to the principal primary endpoint of accuracy. In the RAMP-1 trial, the trial with the relatively lower risk patient population, the ultrasound blinded readers demonstrated superior specificity (the measure of effectiveness in assessing the absence of disease) compared to nuclear stress. In the RAMP-2 trial, the trial with the relatively higher risk patient population, the ultrasound blinded readers demonstrated superior sensitivity (the measure of effectiveness in assessing disease) compared to nuclear stress. We demonstrated superior specificity in RAMP-1 and superior sensitivity in RAMP-2. Only one of the three ultrasound blinded readers demonstrated non-inferiority to nuclear stress for sensitivity in RAMP-1, and only one of the three ultrasound blinded readers demonstrated non-inferiority to nuclear stress for specificity in RAMP-2. We believe that the missed component primary endpoints in these trials was due largely to the inherent trade-off between sensitivity and specificity caused by “aggressive” and “conservative” ultrasound and nuclear readers. While these component primary endpoints were missed, we believe that both trials demonstrated that, overall, Imagify perfusion stress ultrasound is just as accurate as nuclear stress across all readers. We also believe that because, in addition to achieving the principal primary endpoint in both trials, Imagify perfusion stress ultrasound also demonstrated superior results on component primary endpoints which we believe were the most important in each of these trials (specificity in the lower risk patient population and sensitivity in the higher risk patient population).

We submitted an NDA for Imagify in April 2008 and the NDA was accepted by the FDA for review on June 30, 2008. The FDA acceptance of the NDA submission indicates that the application is sufficiently complete to permit a substantive review and meets the threshold for filing. With a standard review, under the FDA Prescription Drug User Fee Act (PDUFA), the target action date is 10 months from the submission date, or February 28, 2009. The FDA has published a Federal Register Notice on the FDA website of a planned public meeting of the Cardiovascular and Renal Drugs Advisory Committee on December 10, 2008, the agenda of which includes a review of Imagify.

The discussion of our NDA submission and likelihood of success reflects our current assumptions, based on our knowledge and experience and the guidance of our advisors. We cannot assure you that timelines will be met, nor can we assure you that our estimates and assumptions will not change based upon ongoing regulatory feedback or that FDA will approve our NDA. We cannot control nor predict the timing or extent, if any, of FDA approval of Imagify. Nycomed is responsible for the submission of Imagify for approval in Europe. Nycomed’s filing of the MAA for Imagify is currently planned for 2009 due to negative opinion from the
European Medicines Agency (“EMEA”) on pediatric waiver. Recently enacted European legislation requires applicants to provide a plan for the conduct of pediatric studies (Pediatric Investigational Plan) for all new drugs or obtain a waiver for such requirement before a MAA filing is accepted by EMEA. Nycomed’s initial request for a pediatric waiver was denied by the EMEA. We cannot control nor predict the timing or extent, if any, of Imagify approval in Europe or elsewhere.

Imagify Manufacturing Facility Update

As part of our NDA submission for Imagify, we have demonstrated that we can manufacture Imagify at commercial scale and have validated the process in accordance with European regulatory requirements.

In late 2005 we substantially completed the build-out of a 58,000 square foot commercial manufacturing facility in Tewksbury, Massachusetts. In 2006 we completed commissioning of the manufacturing equipment and utilities, produced full commercial scale development batches of Imagify and substantially completed all Installation Qualification, or IQ, and Operational Qualification, or OQ, requirements relating to the equipment and utilities initially needed for this facility. In 2007, we continued to make progress on the remaining steps toward the qualification of the manufacturing facility, with aseptic validation completed in early 2008. We have completed the process validation batches in preparation for Nycomed’s MAA submission in Europe. Data from the production of Imagify at commercial scale and the aseptic validation data were included in our NDA submission of Imagify. We believe that our existing facilities are adequate to meet our current and initial projected commercial requirements and that suitable space will be available as needed. We are currently preparing our manufacturing facility for a Pre-Approval Inspection to be conducted by the FDA prior to the PDUFA date in late 2008 or early 2009.

Operational Activities Update

Our current operational activities include:

**NDA/MAA**: We completed aseptic validation in early 2008. We submitted our NDA for Imagify with FDA in April 2008 and the NDA was accepted by the FDA for review on June 30, 2008. The FDA acceptance of the NDA submission indicates that the application is sufficiently complete to permit a substantive review and meets the threshold for filing. With a standard review, under the FDA Prescription Drug User Fee Act (PDUFA), the target action date is 10 months from the submission date, or February 28, 2009 which we refer to as our “PDUFA Date”. We submitted the NDA in electronic CTD format, which can also be utilized for submission in Europe, and are currently responding to FDA questions arising from their review of the NDA and preparing for the FDA Cardiovascular and Renal Drugs Advisory Committee meeting on December 10, 2008. We are currently preparing our manufacturing facility for a Pre-Approval Inspection to be conducted by FDA prior to the PDUFA date in late 2008 or early 2009. We have completed the process validation batches in preparation for the MAA submission by Nycomed, our European partner. Nycomed’s filing of the European MAA is currently planned for 2009.

**Preparations for Commercialization of Imagify After the PDUFA date**: We plan to conduct market research and advance our plans for the commercial launch of Imagify, including conducting various clinical trials designed to support the commercialization of Imagify.

**Publication of Imagify Results**: In November 2007 we presented data from the RAMP-1 and RAMP-2 clinical trials at the annual American Heart Association meeting in Orlando, Florida and in December 2007, at EuroECHO 2007 in Lisbon, Portugal. We will continue to work with the clinical investigators to publish further data on our clinical trial results.

**Agreements with Cephalon**: In March 2008 we entered into a license agreement with Cephalon, Inc. or Cephalon providing Cephalon with an exclusive, worldwide license to our Hydrophobic Drug Delivery System (HDDS) for oncology applications, along with the rights to AI-850, our patented formulation of paclitaxel, in exchange for a cash payment of $10.0 million. The term of this license agreement extends until the expiration of the last of the patent rights licensed under this agreement. This product development candidate, AI-850, and Abraxane™, a registered trademark of Abraxis Bioscience, Inc., have comparable pharmacokinetic profiles based upon human data available in publications on each drug. AI-850 is our patented formulation of paclitaxel, the active ingredient in Abraxane™. Drug product candidates that are confirmed to have equivalent pharmacokinetics in a human study may be eligible for regulatory approval as a bioequivalent and the development timeline is accelerated, since Phase 2 and Phase 3 human clinical trials are not required.

In November 2008, we entered into a license agreement with Cephalon providing Cephalon with an exclusive worldwide license to AI-525, a preclinical-stage injectable formulation of celecoxib using our proprietary Hydrophobic Drug Delivery System (HDDS™)
technology, in exchange for an upfront cash payment of $5 million, a milestone payment of $15 million upon our receipt from the FDA of final approval of the first New Drug Application or NDA prepared by us with respect to celecoxib for any indication, and certain royalty payments based on future sales by Cephalon of celecoxib. The term of this license agreement extends until the expiration of the last of the patent rights licensed under the agreement.

In connection with this November 2008 transaction we issued Cephalon a $15 million senior secured convertible note pursuant to a note purchase agreement, which agreement provides Cephalon with preemptive rights on future equity issuances by Acusphere as well as certain restrictive covenants regarding the conduct of our business, in each case for so long as the Cephalon convertible note remains outstanding or Cephalon holds at least 25% or more of our outstanding voting securities, which period we refer to as the restricted period. In addition, from and after the conversion of the Cephalon convertible note and for so long as Cephalon holds at least 25% or more of our outstanding voting securities, Cephalon will have the right to designate that number of directors to our board of directors that is proportional to its equity interest, provided that any future transaction between us and Cephalon must be approved by a committee of directors consisting entirely of directors that are independent of Cephalon.

The Cephalon convertible note includes an annual interest rate of 8.0% payable annually over three years in cash or shares of our common stock at our election. The Cephalon convertible note is secured by certain of our assets, including all of our intellectual property. The Cephalon convertible note is subject to acceleration and an increased interest rate upon the happening of customary events of default, including the failure to make timely payments of principal and interest.

The Cephalon convertible note is convertible at Cephalon’s option any time prior to November 3, 2009 into one of the following: (i) the greater of (A) the number of shares of our common stock equal to $15 million divided by 90% of $.486 (subject to customary adjustments for stock splits and similar events) or (B) the number of shares of our common stock equal to 51% of our outstanding common stock on a fully-diluted basis on the date of conversion of the Cephalon convertible note, (ii) the right to enter into an exclusive license to all of our intellectual property rights relating to Imagify to use, distribute and sell Imagify for all current and future indications including coronary heart disease, in a worldwide territory, excluding those European countries for which Nycomed has rights pursuant to our collaboration agreement with Nycomed, or (iii) the satisfaction of Cephalon’s obligation to pay us the $15 million milestone payment for approval of celecoxib by the FDA for any indication pursuant to the celecoxib license agreement described above. In connection with the possible conversion of the Cephalon convertible note into shares of our common stock, we also entered into a registration rights agreement with Cephalon pursuant to which we have agreed to register for resale shares of our common stock held by Cephalon.

If Cephalon elects to convert the Cephalon convertible note into the right to enter into the Imagify license, we will be entitled to a $40 million regulatory milestone payment upon final FDA approval of the first NDA for Imagify for the detection of coronary artery disease and certain royalty payments based on future sales by Cephalon of Imagify. The term of the Imagify would extend until the expiration of the last of the patent rights licensed under such agreement.

In addition, if Cephalon elects to convert the Cephalon convertible note into the right to enter into the Imagify license, it may elect to manufacture Imagify itself or it may require Acusphere to manufacture Imagify at a cost no greater than our actual fully burdened manufacturing cost.

Although we are working towards the achievement of these operational objectives, there can be no assurance that we will successfully achieve these objectives in a timely or successful manner, or that they will be achieved at all. In particular, in light of our current capital constraints and need to preserve capital to fund operations, our ability to achieve these operational objectives will be adversely affected unless and until we are able to obtain additional financing.

**European Collaboration Agreement**

In July 2004, we entered into a collaboration, license and supply agreement with Nycomed pursuant to which we granted Nycomed rights to develop and market Imagify in Europe. As part of the agreement, Nycomed agreed to provide up to $70.0 million in license fees, research and development funding, and milestone payments, of which $12.0 million for research and development has been received. In October 2005 and February 2006, we amended the agreement with Nycomed, and an additional $2 million was received for trademark and other activities associated with the qualification of our manufacturing facility. In connection with our agreement with Nycomed, Nycomed has agreed to pay us to manufacture Imagify for them and to pay us royalties on Nycomed’s sales of Imagify. In June 2008, we further amended our agreement again, and Nycomed agreed to reimburse us for expenses related to our qualification of our commercial manufacturing facility in Tewksbury, Massachusetts up to $750,000 which shall be credited against
their initial purchases of Imagify. In September 2008, we again amended our agreement with Nycomed. This amendment removed a contingency associated with $2.0 million worth of additional payments. The payments received pursuant to these amendments are considered advances against future milestone payments, and have been deducted from the $58 million in remaining milestone payments. Therefore, we are entitled to receive $56 million in remaining milestone payments, of which the next payment is due upon the first commercial sale of Imagify. Nycomed will be responsible for sales, marketing and the regulatory submissions required for marketing Imagify throughout its sales territory, which includes the member states of the European Union, as well as Russia/CIS Jurisdictions and Turkey.

The Nycomed agreement is subject to termination provisions. Under certain of these termination provisions, if we fail in any material respect to use all commercially reasonable efforts to carry out our obligations under the agreement, we would be obligated to pay Nycomed liquidated damages of up to $12.0 million. We believe we have and continue to use all commercially reasonable efforts to fulfill our obligations under the agreement, which we believe are in our control. However, there can be no assurance that termination of this agreement will not occur or that such termination would not result in us incurring liquidated damages of up to $12.0 million.

Financial Operations Overview

Revenue. We have not generated any revenue from product sales since our inception. Since July 2004, when we entered into our collaboration agreement with Nycomed, the majority of our revenue has been collaboration revenue recognized in connection with research and development activities performed under this agreement. As of September 30, 2008 Nycomed had paid us $14.0 million in license fees and for our research and development efforts. We are recognizing this $14.0 million of initial license and research and development payments ratably over a period currently estimated at 66 months. The length of this research and development period, which is the period over which we are obligated to perform services, is estimated based on available facts and circumstances. We periodically evaluate the assumptions underlying our estimate and change our estimate when appropriate.

Under the March 2008 intellectual property license agreement with Cephalon, Inc., we received $10.0 million and began recognizing revenue in the second quarter of 2008 over the remaining term of the agreement, which extends until expiration of the last of the patents licensed under the agreement, or approximately 13 years. The Chairman, founder and CEO of Cephalon is also the current Presiding Director of the Board of Directors of the Company. Martyn Greenacre is a member of the Board of Directors of both the Company and Cephalon.

In the future, we will seek to generate revenue from a combination of product sales, up-front or milestone payments and manufacturing payments in connection with collaborative or strategic relationships, and royalties resulting from the license of our products and intellectual property.

Research and Development Expense. Research and development expense consists of expenses incurred in developing, manufacturing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers in conjunction with independently monitoring our clinical trials and acquiring and evaluating data in conjunction with our clinical trials, costs of materials used in clinical trials and research and development, depreciation of capital resources used to develop our products, costs of facilities, the legal costs of pursuing patent protection on select elements of our intellectual property, costs for intellectual property rights we have acquired or licensed and stock-based compensation. We expense research and development costs, including patent related costs, as incurred. We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to realize the potential of our product candidates and proprietary technologies. Development programs for later stage product candidates, such as Imagify, tend to cost more than earlier stage programs due to the length and the number of patients enrolled in clinical trials for later stage programs and due to costs of scaling production to commercial scale.

General and Administrative Expense. General and administrative expense consists primarily of salaries and other related costs for personnel in executive, finance, accounting, information technology, business development and human resource functions. Other costs include facility costs not otherwise included in research and development expense, professional fees for legal and accounting services and stock-based compensation. In addition, we categorize our market research and other marketing-type costs as general and administrative expense because we have not yet obtained approval to market or sell our product candidates.

Interest Income. Interest income consists of interest earned on our cash and cash equivalents.

Interest Expense. Interest expense consists primarily of interest incurred on equipment leases, equipment loans and other financing arrangements.
Change in Valuation of Derivative.  The terms of our February 2005 convertible preferred stock offering and our March 2005 Mass Development loan agreement contain features considered to be embedded derivatives which are recorded at estimated fair value in accordance with Statement of Financial Accounting Standards No. 133, Accounting for Derivative Instruments (SFAS 133). Change in valuation of derivative consists of other income (expense) recognized on the change in fair value of the derivative at the end of each reporting period. The change in the value of the embedded derivative related to the preferred stock is affected by a number of assumptions including the number of preferred shares outstanding, the amount of dividends paid and the probability and timing of conversion into common stock. The derivative liability is reduced for any make-whole payments made during the period upon conversions of preferred stock to common stock. The change in the value of the derivative related to the loan is affected by the expected timing of future positive net cash flows from operations.

Dividends on Preferred Stock.  For the nine months ended September 30, 2008 and 2007, dividends on preferred stock consisted of dividends paid or accumulated on the convertible exchangeable preferred stock which we issued in February 2005. Dividends on preferred stock exclude any make-whole payments on conversion of preferred stock to common stock. Dividends on our preferred stock are cumulative from the date of original issue at the annual rate of $3.25 per share, payable quarterly on the first day of March, June, September, and December. Any dividend payment must be declared by our board of directors and must come from funds that are legally available for dividend payments. In February 2008 and May 2008, our Board of Directors did not declare the quarterly dividend on the preferred stock, payable on March 1, 2008 and June 1, 2008, respectively. In August 2008, our Board of Directors again elected not to declare a quarterly cash dividend in the amount of $0.8125 per share on the preferred stock that was otherwise payable on September 1, 2008. This is the third quarterly dividend that has not been declared and paid on the preferred stock. Under the terms of the preferred stock, the holders thereof shall be entitled to vote as a separate class to elect two directors if we have not paid the equivalent of six or more quarterly dividends, whether or not consecutive. These voting rights will continue until we pay the full accrued but unpaid dividends on the preferred stock. The dividend payable on September 1, 2008 totaled $0.4 million in the aggregate. Cumulative dividends payable of $0.8 million have been included in current liabilities as of September 30, 2008.

Results of Operations

Three Months Ended September 30, 2008 and 2007

Revenue. In connection with our collaboration agreement with Nycomed entered into in July 2004, Nycomed has paid us $12.0 million in license fees for our research and development efforts. We had previously been recognizing this $12.0 million in research and development payments ratably over the estimated development period, as defined, of 54 months. Estimation of this development period involves many assumptions. We regularly assess these assumptions and our estimated development recognition period may change if facts and circumstances change. We reevaluated the assumptions underlying the development term and during the three months ended September 30, 2008, modified our estimate of the development period over which we are obligated to perform services to 66 months. Collaboration revenue recognized under this agreement for the three months ended September 30, 2008 was approximately $0.2 million and in 2007 was approximately $0.7 million.

Under the March 2008 intellectual property license agreement with Cephalon, Inc., revenue began to be recognized in the second quarter of 2008 over the remaining term of the agreement, which extends until expiration of the last of the patents licensed under the agreement, or approximately 13 years. We recognized revenue for the three months ended September 30, 2008 of approximately $0.2 million under this agreement.

Research and Development Expense. Research and development expense for the three months ended September 30, 2008 decreased $4.2 million, or 36%, to $7.5 million versus $11.7 million in the prior year period. The decrease was primarily due to lower costs of early stage development programs as we increase our focus on supporting our Imagify NDA and MAA submissions.

The following table summarizes the primary components of our research and development expense for the three months ended September 30, 2008 and 2007:

<table>
<thead>
<tr>
<th>Component</th>
<th>2008</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imagify</td>
<td>$3,101</td>
<td>$5,509</td>
</tr>
<tr>
<td>HDSS and PDDS</td>
<td>89</td>
<td>1,683</td>
</tr>
<tr>
<td>Other direct costs</td>
<td>813</td>
<td>991</td>
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<tr>
<td>Total direct costs</td>
<td>$4,003</td>
<td>$8,183</td>
</tr>
<tr>
<td>Indirect costs:</td>
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<td></td>
</tr>
<tr>
<td>Facility rent costs</td>
<td>844</td>
<td>862</td>
</tr>
<tr>
<td>Depreciation</td>
<td>2,476</td>
<td>2,474</td>
</tr>
<tr>
<td>Other indirect costs</td>
<td>180</td>
<td>209</td>
</tr>
<tr>
<td>Total indirect costs</td>
<td>3,500</td>
<td>3,545</td>
</tr>
<tr>
<td>Total research and development expense</td>
<td>$7,503</td>
<td>$11,728</td>
</tr>
</tbody>
</table>

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Late Stage Clinical Development Program (Imagify). Our lead product candidate, Imagify, is a cardiovascular drug designed for the detection of coronary artery disease. Direct expense for research and development of Imagify was $3.1 million for the three months ended September 30, 2008 versus $5.5 million in 2007. Clinical trial costs relating to Imagify pivotal trials decreased in 2008 versus 2007, following the release of RAMP-2 results in May 2007.

Early Stage Development Programs (HDDS and PDDS). During 2008, we anticipate the costs of early stage development programs to decrease as we increase our focus on supporting our Imagify NDA and MAA submissions. Because these other programs are in relatively early stages of development, we anticipate that costs related to Imagify will continue to represent our primary research and development expenditures through 2008.

Other Costs. Other direct research and development costs primarily consist of management and preclinical evaluation of other product candidates.

Each of our research and development programs is subject to risks and uncertainties, including the requirement to seek regulatory approvals, which are outside of our control. Moreover, the product candidates identified in these research and development programs, particularly our early stage programs, must overcome significant technological, manufacturing and marketing challenges before they can be successfully commercialized. As a result of these risks and uncertainties, we are unable to predict with any certainty the period in which material net cash inflows from such projects could be expected to commence or the completion date of these programs. Failure to commercialize these product candidates on a timely basis could have a material adverse affect on our business, financial condition and results of operations. We may seek to establish collaborative relationships to help us commercialize these product candidates, but there can be no assurance that we will be successful in doing so.

General and Administrative Expense. General and administrative expense for the three months ended September 30, 2008 was $2.8 million, versus $3.1 million in the prior year period, a decrease of $0.3 million or 10%. The decrease was due to lower consulting costs in marketing.

The following table summarizes the primary components of our general and administrative expense for the three months ended September 30, 2008 and 2007:

<table>
<thead>
<tr>
<th>Three Months Ended September 30,</th>
<th>2008 (In thousands)</th>
<th>2007 (In thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct costs</td>
<td>$ 2,526</td>
<td>$ 2,910</td>
</tr>
<tr>
<td>Indirect costs:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility costs</td>
<td>219</td>
<td>130</td>
</tr>
<tr>
<td>Depreciation</td>
<td>27</td>
<td>52</td>
</tr>
<tr>
<td>Total indirect costs</td>
<td>246</td>
<td>182</td>
</tr>
<tr>
<td>Total general and administrative expense</td>
<td>$ 2,772</td>
<td>$ 3,092</td>
</tr>
</tbody>
</table>

Interest Income. Interest income for the three months ended September 30, 2008 decreased approximately $0.5 million, or 83%, to approximately $0.1 million versus $0.6 million in the prior year period. The decrease was due to lower average cash balances during the period.

Interest Expense. Interest expense for the three months ended September 30, 2008 decreased $0.2 million, or 40%, to $0.3 million versus $0.5 million in the prior year period. The decrease is due to lower average loan balances during the period as a result of repayments of the capital equipment loans.
Change in Valuation of Derivative. The derivative is related to the embedded derivative instrument from the dividend make-whole payment feature of the preferred stock offering that closed in February 2005. The derivative liability value is reduced as dividends payments on the preferred stock are made, as well as for any conversions of preferred stock into common stock. The derivative liability at September 30, 2008 was valued at $64,000.

Nine Months Ended September 30, 2008 and 2007

Revenue. In connection with our collaboration agreement with Nycomed entered into in July 2004, Nycomed has paid us $12.0 million in license fees for our research and development efforts. We had previously been recognizing this $12.0 million in research and development payments ratably over the estimated development period, as defined, of 54 months. Estimation of this development period involves many assumptions. We regularly assess these assumptions and our estimated development recognition period may change if facts and circumstances change. We reevaluated the assumptions underlying the development term and during the three months ended September 30, 2008, modified our estimate of the development period over which we are obligated to perform services to 66 months. Collaboration revenue recognized under this agreement for the nine months ended September 30, 2008 and 2007 was $1.5 million and $2.0 million, respectively.

Under the March 2008 intellectual property license agreement with Cephalon, Inc., revenue began to be amortized in the second quarter of 2008 over the remaining term of the agreement, which extends until expiration of the last of the patents licensed under the agreement, or approximately 13 years. We recognized revenue for the nine months ended September 30, 2008 of approximately $0.3 million under this agreement.

Research and Development Expense. Research and development expense for the nine months ended September 30, 2008 decreased $5.4 million, or 17%, to $27.2 million versus $32.6 million in the prior year period. The decrease was due to a planned delay in early stage development programs as we focus on supporting our Imagify NDA and MAA submissions, partially offset by increased manufacturing costs for the Imagify program and also a one time charge for a payment due under an intellectual property agreement.

The following table summarizes the primary components of our research and development expense for the nine months ended September 30, 2008 and 2007:

<table>
<thead>
<tr>
<th></th>
<th>Nine Months Ended September 30, 2008 (In thousands)</th>
<th>2007 (In thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imagify</td>
<td>$13,215</td>
<td>$15,175</td>
</tr>
<tr>
<td>HDDS and PDDS</td>
<td>270</td>
<td>3,558</td>
</tr>
<tr>
<td>Other direct costs</td>
<td>2,383</td>
<td>3,041</td>
</tr>
<tr>
<td>Total direct costs</td>
<td>$15,868</td>
<td>$21,774</td>
</tr>
<tr>
<td>Indirect costs:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility rent costs</td>
<td>2,534</td>
<td>2,613</td>
</tr>
<tr>
<td>Depreciation</td>
<td>7,432</td>
<td>7,420</td>
</tr>
<tr>
<td>Other indirect costs</td>
<td>1,377</td>
<td>764</td>
</tr>
<tr>
<td>Total indirect costs</td>
<td>11,343</td>
<td>10,797</td>
</tr>
<tr>
<td>Total research and development expense</td>
<td>$27,211</td>
<td>$32,571</td>
</tr>
</tbody>
</table>

Late Stage Clinical Development Program (Imagify). Our lead product candidate, Imagify, is a cardiovascular drug designed for the detection of coronary artery disease. Direct expense for research and development of Imagify was $13.2 million for the nine months ended September 30, 2008 versus $15.2 million in 2007. Clinical trial costs relating to Imagify pivotal trials decreased in 2008 versus 2007, following the release of RAMP-2 results in May 2007.

Early Stage Development Programs (HDDS and PDDS). During 2008, we anticipate the costs of early stage development programs to decrease as we increase our focus on supporting our Imagify NDA and MAA submissions. Because these other programs are in relatively early stages of development, we anticipate that costs related to Imagify will continue to represent our primary research and development expenditures through 2008.

Other Costs. Other direct research and development costs primarily consist of management and preclinical evaluation of other product candidates.
Each of our research and development programs is subject to risks and uncertainties, including the requirement to seek regulatory approvals, which are outside of our control. Moreover, the product candidates identified in these research and development programs, particularly our early stage programs, must overcome significant technological, manufacturing and marketing challenges before they can be successfully commercialized. As a result of these risks and uncertainties, we are unable to predict with any certainty the period in which material net cash inflows from such projects could be expected to commence or the completion date of these programs. Failure to commercialize these product candidates on a timely basis could have a material adverse affect on our business, financial condition and results of operations. We may seek to establish collaborative relationships to help us commercialize these product candidates, but there can be no assurance that we will be successful in doing so.

General and Administrative Expense. General and administrative expense for the nine months ended September 30, 2008 decreased by $1.1 million, or 11% to $8.6 million versus $9.7 million in the prior period. The decrease is primarily due to lower salary costs and consulting costs in marketing.

The following table summarizes the primary components of our general and administrative expense for the nine months ended September 30, 2008 and 2007:

<table>
<thead>
<tr>
<th></th>
<th>Nine Months Ended September 30, 2008 (In thousands)</th>
<th>2007 (In thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct costs</td>
<td>$7,848</td>
<td>$9,116</td>
</tr>
<tr>
<td>Indirect costs:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility costs</td>
<td>635</td>
<td>390</td>
</tr>
<tr>
<td>Depreciation</td>
<td>112</td>
<td>163</td>
</tr>
<tr>
<td>Total indirect costs</td>
<td>747</td>
<td>553</td>
</tr>
<tr>
<td>Total general and administrative expense</td>
<td>$8,595</td>
<td>$9,669</td>
</tr>
</tbody>
</table>

Interest Income. Interest income for the nine months ended September 30, 2008 decreased $1.6 million, or 84%, to $0.3 million versus $1.9 million in the prior year period. The decrease was due to lower average cash balances during the period.

Interest Expense. Interest expense for the nine months ended September 30, 2008 decreased $0.5 million, or 31%, to $1.1 million versus $1.6 million in the prior year period. The decrease is due to lower average loan balances during the period as a result of repayments of the capital equipment loans.

Change in Valuation of Derivative. The derivative is related to the embedded derivative instrument from the dividend make-whole payment feature of the preferred stock offering that closed in February 2005. The derivative liability value is reduced as dividends payments on the preferred stock are made, as well as for any conversions of preferred stock into common stock. The derivative liability at September 30, 2008 was valued at $64,000.

Liquidity and Capital Resources

Historically, we have financed our business through the issuance of equity securities, debt financings and equipment leases and, more recently, with funds from our collaborations with Nycomed and Cephalon. Our liquidity requirements have arisen primarily from research and development expenditures, equipment expenditures and payments on outstanding indebtedness. As of September 30, 2008, we had cash and cash equivalents of $4.1 million. As of September 30, 2008 we owed approximately $0.1 million for capital leases and $12.4 million for notes payable and other long-term obligations. We also had operating lease commitments totaling $11.1 million for rent of our facilities.

On November 3, 2008, we closed a transaction with Cephalon which provided $20 million in upfront funding in the form of a $15 million senior secured convertible note and receipt of a $5 million upfront fee for an exclusive worldwide license to AI-525, a preclinical-stage injectable formulation of celecoxib using the Company’s proprietary Hydrophobic Drug Delivery System (HDDS™) technology.

We expect that our existing resources, together with funds from the Cephalon transaction will fund operations into but not beyond the second quarter of 2009. We will require significant additional funds in order to continue to fund our operations through and beyond the second quarter of 2009. We may raise these funds through public or private sales of equity, or from borrowings, or from strategic partners. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development activities and the size and timing of creating expanded manufacturing capabilities. We do not expect to generate significant revenues from Imagify, other than possible license or milestone payments, unless or until we or current or potential
partners submit an application for and receive marketing approval from the applicable regulatory authorities. The depletion of our resources may make future funding more difficult or expensive to attain. When additional funds are required or, in advance of such requirements, we may raise such funds from time to time through public or private sales of equity or from borrowings or from strategic partners or we may delay funding of certain development activities which could delay the approval and/or commercialization of Imagify, which would have a negative impact on our growth plans. We are evaluating our funding alternatives. Additional equity financing will be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; and strategic partnerships may result in royalties or other terms which reduce our economic potential from products under development, including Imagify. Since our present capital resources are not sufficient to fund our planned operations through and beyond the second quarter of 2009, substantial doubt about our ability to continue as a going concern exists without successfully raising funds as described above. If we are unable to execute our operations according to our plans or to obtain additional financing, we may be forced to cease operations.

During the nine months ended September 30, 2008, operating activities used approximately $17.1 million of cash. Net cash used by operating activities during this period resulted primarily from a net loss of $34.8 million, partially offset by an increase in deferred revenue of $10.8 million as a result of the license agreement with Cephalon, Inc. and an amendment to the Nycomed Agreement and non-cash charges for depreciation, amortization and stock based compensation of $9.0 million.

During the nine months ended September 30, 2008, investing activities used approximately $0.1 million of cash. This use of cash was primarily used for purchases of equipment incurred in connection with our commercial manufacturing facility for Imagify.

During the nine months ended September 30, 2008, financing activities used $4.8 million in cash, primarily due to payments on long term obligations.

We presently estimate that the total quarterly cash outflows for the remainder of 2008 to be approximately $8 to $9 million.

On July 28, 2008, we eliminated 24 positions or approximately twenty-four percent (24%) of its workforce and began notifying the affected employees. In addition, pursuant to the Senior Management Compensation Plan approved by the Compensation Committee of the our Board of Directors on July 25, 2008, all senior managers at the Vice President level and above have taken salary reductions of 10% or more, to further decrease operating costs while the Company awaits FDA review of its NDA for Imagify. The salary reductions were effective on August 1, 2008. In connection with this reduction, incurred a pre-tax costs in the third quarter of 2008 of approximately $0.3 million, which is related to severance and benefit costs. The total annualized pre-tax cost savings that are expected to result from this reduction and the salary reductions described above are estimated to be approximately $2.1 million. In addition, the termination of certain of our outside consultants and contractors will result in estimated annual savings of approximately $2.0 million. Although we believe that our estimates are appropriate and reasonable based on available information, actual results could differ from these estimates.

Our current vacation policy allows employees to carry over unused vacation time as of December 31 of each year, up to a maximum of two weeks. However, several employees who joined Acusphere prior to the institution of this vacation policy had accumulated more than two weeks vacation at December 31, 2007. These employees had been allowed to carry this excess vacation accrual forward each year. In April 2008 approximately $0.7 million of this accumulated vacation liability to employees was paid in a lump sum payment.

Our current vacation policy allows employees to carry over unused vacation time as of December 31 of each year, up to a maximum of two weeks. However, several employees who joined Acusphere prior to the institution of this vacation policy had accumulated more than two weeks vacation at December 31, 2007. These employees had been allowed to carry this excess vacation accrual forward each year. In April 2008 approximately $0.7 million of this accumulated vacation liability to employees was paid in a lump sum payment.

On May 15, 2008, we entered into a second amendment (the “Second GE Amendment”) to the GE patent license agreement. Under the First amendment with GE (the “First GE Amendment”), we were due to make a series of six (6) consecutive quarterly installments of approximately $0.9 million due on the first day of the third month of each calendar quarter, commencing on June 1, 2008. The Second GE Amendment provides that, in lieu of these payments, we shall make a series of payments due as follows: $5.5 million due as of June 1, 2007, payable in two installments commencing on June 1, 2008, the first installment of approximately $0.9 million is due on June 1, 2008 and was paid in May 2008 and the remaining installment is due and payable on October 1, 2009 in an amount consisting of (i) the amount of approximately $4.6 million in principal plus (ii) interest accruing on such principal amount from July 1, 2008 at the rate of 6% per annum until paid in full. If receipt of regulatory approval by the U.S. Food and Drug Administration to market Imagify in the United States, or the approval of a Marketing Authorization Application to market Imagify in Europe, is received prior to the October 1, 2009 due date, any then remaining balance of the approximately $4.6 million (plus interest accrued to such date) payable as described above shall be immediately due and payable in full. The current carrying value of the later payment has been included in the current portion of long-term obligations at September 30, 2008.
On May 15, 2008, we entered into a second amendment (the “Second BSP Amendment”) to the Schering patent transfer agreement. Under the First BSP Amendment, we were due to make a payment of $1.0 million to Schering on or before fifteen days after May 11, 2008 and a payment of another $1.0 million to Schering on or before fifteen days after May 11, 2009. The Second BSP Amendment provides that, in lieu of these payments, we shall make a series of payments due as follows: $200,000 on or before fifteen days following execution of the Second BSP Amendment and $1.8 million on or before fifteen days after May 11, 2009. The $200,000 payment was paid in May 2008 and the current carrying value of the remaining $1.8 million has been included in the current portion of long-term obligations at September 30, 2008.

In March 2008 we entered into a license agreement with Cephalon, Inc. (“Cephalon”) providing Cephalon with an exclusive, worldwide license to the Company’s Hydrophobic Drug Delivery System (HDDS) for oncology applications, along with the rights to AI-850, our formulation of paclitaxel, in exchange for a cash payment of $10.0 million, paid upon the execution of the agreement. The term of the agreement extends until expiration of the last of the patents licensed under the agreement. We have recorded this payment in deferred revenue at September 30, 2008, and will recognize it as income ratably over the remaining estimated useful life of the patents, or approximately 13 years.

Effective June 1, 2006, we entered into an agreement to license on a non-exclusive basis various ultrasound-related intellectual property from Bracco International BV, or Bracco. In consideration for the non-exclusive license of these patents, we agreed to pay Bracco up to a total of Euros 3.0 million, of which Euros 0.5 million (approximately $0.6 million) was paid in June 2006. On July 29, 2008, we entered into an amendment (the “Amendment”) to the Bracco patent license agreement. Under the Bracco patent license agreement, we were obligated to make a payment of Euros 500,000 (approximately $0.8 million) to Bracco within five business days after the acceptance by the FDA of a new drug application filing package for Imagify. The FDA accepted our application on June 30, 2008, making such payment to Bracco due on July 8, 2008. The Amendment reduces the amount of the payment due on July 8, 2008 to Euros 100,000 (approximately $0.2 million), and provides that an additional payment of Euros 400,000 (approximately $0.6 million) will be due on the first anniversary of such acceptance by the FDA, or June 30, 2009. The Amendment further provides that we grant Bracco a perpetual non-exclusive and royalty-free right and license within the field of ultrasound diagnostic imaging to use and exploit any intellectual property that we have developed or may develop after June 1, 2006 which relates to, or to the use or performance of, the patents licensed by Bracco under the Agreement. We have paid this Euro 100,000 (approximately $0.2 million) in August 2008 and the additional payment of Euros 400,000 (approximately $0.6 million) that is due on the first anniversary of such acceptance by the FDA, or June 30, 2009 has been included in current liabilities as of September 30, 2008. An additional Euros 2.0 million is payable upon our achievement of certain defined regulatory milestones. We also agreed to pay a royalty on future Imagify revenue, up to a maximum royalty amount of Euros 10.0 million, less a portion of the above-referenced milestone payments. Whereas the other obligations are contingent upon the outcome of future events, they have not been recorded at this time.

On each of May 18, 2007, March 28, 2007 and January 5, 2007, we entered into promissory notes under an equipment financing line with General Electric Capital Corporation (“GE Capital”) each of which totaling in aggregate original principal amount approximately $0.3 million for equipment already purchased by us. The promissory notes include annual interest rates of 10.55%, 10.41% and 10.60%, respectively, and are payable over 42 consecutive months. The promissory notes are secured by the equipment financed pursuant to the terms of our Master Security Agreement with GE Capital. The notes are subject to acceleration upon certain events of default, including but not limited to: i) the failure to make timely payments of principal and interest, ii) a default on other material obligations, or iii) a material adverse change in the financial condition of the borrower.

In June 2005, we entered into an equipment financing line with Oxford Finance Corporation, (“Oxford”). In 2005 and 2006, we borrowed an aggregate of $7.0 million against this line. As of September 30, 2008, net of repayments, we had $2.0 million outstanding under this line. Such borrowings are collateralized by corresponding equipment and other capital purchases with repayment due in monthly installments over 36 to 48 months, depending on the nature of the equipment financed, with the last such repayment scheduled for March 2010. Interest rates on these borrowings were fixed at the time of each borrowing and range from 10.3% to 10.9%. The loans under this line are subject to acceleration upon certain events of default, including but not limited to the failure to make timely payments of principal and interest, a default on other material obligations, or a material adverse change in the financial condition of the borrower.

In March 2005 we borrowed $2.0 million under a loan agreement with MassDevelopment to help finance certain tenant improvements to its commercial manufacturing facility in Tewksbury, Massachusetts. The loan is secured by certain improvements made at the facility, interest accrues at 5.0% per annum with retroactive adjustments to 9.0% in the event the we achieve positive operating cash flow, as defined in the agreement, prior to repayment of the loan. Accrued principal and interest are being repaid over a 10 year term. The loan is subject to acceleration upon certain customary events of default, including failure to timely pay principal and interest. We
began making payments on this loan in May 2007 and as of September 30, 2008, have approximately $2.1 million outstanding under the loan, including principal and interest.

In February 2005, we issued 900,000 shares of 6.5% convertible exchangeable preferred stock, our Preferred Stock, at $50.00 per share resulting in net proceeds of approximately $41.9 million after deducting underwriting discounts, commissions and offering expenses. Each share of Preferred Stock has a liquidation preference of $50.00 per share. Dividends on the Preferred Stock are cumulative from the date of original issue at the annual rate of $3.25 per share, payable quarterly on the first day of March, June, September, and December. Any dividends must be declared by our board of directors and must come from funds that are legally available for dividend payments. During the nine months ended September 30, 2008 and 2007, we paid $0 and $1.7 million, respectively, in dividends on our Preferred Stock. As of September 30, 2008, 480,000 shares of Preferred Stock were outstanding, accrued and unpaid dividends totaled approximately $0.8 million.

In February 2008 and May 2008, our Board of Directors elected not to declare a quarterly cash dividend that was otherwise payable on March 1, 2008 and June 1, 2008, respectively. On August 24, 2008, our Board of Directors again elected not to declare a quarterly cash dividend in the amount of $0.8125 per share on the preferred stock that was otherwise payable on September 1, 2008. This is the third quarterly dividend that has not been declared and paid on the preferred stock. This dividend payable on September 1, 2008, which would have totaled $0.4 million in the aggregate. The total of $0.8 million has been included in current liabilities as of September 30, 2008. If we have not paid dividends on the preferred stock in an aggregate amount equal to at least six quarterly dividends whether or not consecutive, we must increase the size of our Board of Directors by two additional directors. After this time, and for so long as these dividends remain due and unpaid, holders of the Preferred Stock, voting separately as a class with holders of Preferred Stock ranking on the same basis as to dividends having like voting rights, will be entitled to elect two additional directors at any meeting of stockholders at which directors are to be elected.

We may elect to automatically convert some or all of the Preferred Stock into shares of our common stock if the closing price of our common stock has exceeded $10.30 per share (150% of the conversion price) for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion. Prior to March 1, 2009, if we elect to automatically convert, or if any holder elects to voluntarily convert, the Preferred Stock, we will also make an additional payment, the Make-Whole payment, equal to the aggregate amount of dividends that would have been payable on the Preferred Stock so converted from the original date of issuance through and including March 1, 2009, less any dividends already paid on the Preferred Stock. This additional payment is payable by us, at our option, in cash, in additional shares of its common stock, or in a combination of cash and shares of common stock. We have reserved a maximum of approximately 0.3 million shares of common stock for issuance under this Make-Whole provision.

Through September 30, 2008, 420,000 shares of Preferred Stock have been voluntarily converted into 3,061,223 shares of our common stock. In connection with such conversions, we issued an additional 490,504 shares of our common stock in satisfaction of the required Make-Whole payment.

We may elect to redeem the Preferred Stock at declining redemption prices on or after March 6, 2009. The Preferred Stock is exchangeable, in whole but not in part, at our option on any dividend payment date beginning on the exchange date (March 1, 2006) for our 6.5% convertible subordinated debentures, or the Debentures, at the rate of $50 principal amount of Debentures for each share of Preferred Stock. The Debentures, if issued, will mature 25 years after the exchange date and have terms substantially similar to those of the Preferred Stock.

In April 2004, we entered into an equipment financing line with General Electric Capital Corporation. In 2004 and 2005 we borrowed an aggregate of $10.5 million under the equipment financing line. As of September 30, 2008, net of repayments, we had $2.5 million outstanding. Borrowings are collateralized by the equipment financed with repayment due in monthly installments over 36 to 48 months, with the last such repayment scheduled for December 2010. Interest rates on these borrowings were fixed at the time of each borrowing and range from 8.7% to 10.7%. The loans under this line are subject to acceleration upon certain events of default, including but not limited to: i) the failure to make timely payments of principal and interest, ii) a default on other material obligations, or iii) a material adverse change in the financial condition of the borrower.

In July 2004, we entered into a collaboration, license and supply agreement with Nycomed in which we granted Nycomed rights to develop and market Imagify in Europe. Under the original terms of this agreement, Nycomed paid us license fees and research and development payments totaling $12.0 million. The original agreement also provides for Nycomed to pay to us up to $58.0 million in milestone payments upon achievement of certain milestones. Under the agreement, Nycomed has agreed to pay us to manufacture Imagify for them and to pay us royalties on Nycomed’s sales of Imagify. In October 2005 and February 2006, our agreement with

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Nycomed was amended such that Nycomed paid us an additional $2.0 million for trademark activities and activities associated with the qualification of our manufacturing facility. Subsequently in September 2008, this arrangement with Nycomed was amended. This amendment removed a contingency associated with the $2.0 million of payments. These amendments were considered advances against future milestone payments, and have been deducted from the $58 million in remaining milestone payments. Therefore, we have $56 million remaining in milestone payments. No additional funds are expected from Nycomed under the agreement for the next twelve months. On June 26, 2008, we executed a third amendment to our agreement with Nycomed. Pursuant to the amendment, Nycomed shall reimburse us for expenses arising from and after June 1, 2008 and related to our qualification of our commercial manufacturing facility in Tewksbury, Massachusetts. Such amounts shall not, in the aggregate, exceed $750,000 and are payable by Nycomed upon receipt of monthly invoices. The amendment further provides that $750,000 shall be credited against Nycomed’s initial purchases of Imagify so that Nycomed shall only pay for Imagify delivered after such $750,000 has been fully credited.

Shelf Registration Statement

We have on file with the U.S. Securities and Exchange Commission, or SEC, a “universal shelf” registration statement on Form S-3 (Registration No. 333-134263), which provides for the offer, from time to time, of common stock, preferred stock, debt securities and warrants up to an aggregate remaining availability, as of September 30, 2008, of approximately $33.5 million, subject to our satisfaction of the criteria for use of Form S-3. The SEC declared the shelf registration statement effective on August 18, 2006. SEC rules currently limit our ability to utilize a shelf registration statement to no more than one-third of our unaffiliated public float over any twelve month period. Subject to these limitations, market conditions and our capital needs, and to the extent and so long as we are then eligible to use the registration statements under SEC rules, we may again seek to use any remaining availability under the shelf registration statements by making an offering of securities covered for sale under the registration statements. In addition, we may amend our shelf registration statements or file a new shelf registration statement to increase our potential access to capital. If we elect to raise additional capital using a shelf registration statement, we may use the net proceeds from the sale of these securities for general corporate purposes, which may include funding clinical trials, research and development, regulatory activities, acquisitions, including acquisitions of companies, products, intellectual property or other technology, repayment or refinancing of existing indebtedness, investments, capital expenditures, repurchase of our capital stock and for any other purposes that we may specify in any prospectus supplement.

Off-Balance Sheet Financing Arrangements

We currently do not have any special purpose entities or off-balance sheet financing arrangements other than operating leases.

Contractual Obligations

The following table summarizes our contractual obligations as of September 30, 2008 and the effect such obligations are expected to have on our liquidity and cash flow in future periods:

<table>
<thead>
<tr>
<th>Contractual Obligations</th>
<th>Total</th>
<th>2008</th>
<th>2009 - 2010</th>
<th>2011 - 2012</th>
<th>2013 and Beyond</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-Term Debt</td>
<td>$6,933</td>
<td>1,370</td>
<td>4,130</td>
<td>670</td>
<td>763</td>
</tr>
<tr>
<td>Capital Lease Obligations</td>
<td>50</td>
<td>8</td>
<td>42</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating Lease Obligations</td>
<td>11,060</td>
<td>770</td>
<td>6,092</td>
<td>4,198</td>
<td></td>
</tr>
<tr>
<td>Purchase Obligations</td>
<td>112</td>
<td>112</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Long-Term Obligations</td>
<td>7,310</td>
<td></td>
<td>7,310</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>$25,465</td>
<td>2,260</td>
<td>17,574</td>
<td>4,868</td>
<td>763</td>
</tr>
</tbody>
</table>

Long-Term Debt of $6.9 million includes $2.6 million in principal and interest payable to General Electric Capital Corporation (“GE”) and $2.2 million in principal and interest payable to Oxford Finance Corporation (“Oxford”) under equipment loans with payments due in monthly installments over 36 to 48 months, collateralized by the corresponding equipment. The loans under the GE line are subject to acceleration upon certain events of default, including but not limited to: i) the failure to make timely payments of principal and interest, ii) a default on other material obligations, or iii) a material adverse change in the financial condition of the borrower. The loans under the Oxford line are subject to acceleration upon certain events of default, including but not limited to the failure to make timely payments of principal or a default on other material obligations.
Also included under Long-Term Debt is $2.1 million in principal and interest payments due under the MassDevelopment loan, under which we borrowed $2.0 million to finance improvements to our commercial manufacturing facility in Tewksbury, Massachusetts. Interest accrues under the loan at 5.0% per annum with retroactive adjustments to 9.0% in the event we achieve positive operating cash flow as defined in the agreement without prior repayment of the loan. No payments were due under the loan for the first 24 months and we began loan repayments in May 2007. The loan has a 10 year repayment term and is subject to acceleration upon certain events of default, including failure to timely pay principal and interest.

Capital Lease Obligations as classified pursuant to FASB Statement of Financial Accounting Standards No. 13, Accounting for Leases relate to leases for business equipment. We leased capital equipment through Banc of America Leasing Corporation. The remaining monthly payments range from $460 to $1,019 with maturities through June 2010.

Our operating lease obligations of $11.1 million relate primarily to our headquarters and manufacturing facility leases under which we pay monthly rent. Our Watertown, Massachusetts headquarters lease has an original term of 10 years, which began in December 2001, and which was extended by six months during 2005. The lease for our commercial manufacturing space in Tewksbury, Massachusetts has an initial five year, nine month term, which began in July 2004, with options to extend the lease for up to two additional five-year terms at predetermined rental rates.

Purchase Obligations include one purchase order to a supplier for material.

Other Long-Term Liabilities includes approximately $4.9 million payable to GE Healthcare pursuant to the amended intellectual property license agreement which is due and payable on October 1, 2009 in an amount consisting of (i) the amount of approximately $4.6 million in principal plus (ii) interest accruing on such principal amount from July 1, 2008 at the rate of 6% per annum until paid in full. Other Long-Term Liabilities also includes $1.8 million payable which is due and payable in May 2009 to pursuant to intellectual property acquisition agreement. Other Long-Term liabilities Euro 400,000 (approximately $0.6 million) due on June 30, 2009 to Bracco pursuant to a patent license agreement.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition 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. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an on-going basis, we evaluate our estimates and judgments, including those related to revenues, accrued expenses, fair valuation of stock related to stock-based compensation and income taxes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue. We recognize revenue from license arrangements in accordance with Staff Accounting Bulletin No. 104, Revenue Recognition ("SAB 104") and FASB Emerging Issue Task Force Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables ("EITF 00-21"). We recognize revenue from license payments not tied to achieving a specific performance milestone ratably over the period over which we are obligated to perform services. The period over which we are obligated to perform services is estimated based on the probability of achieving the milestone. We recognize revenue from performance payments, when such performance is substantially in our control and when we believe that completion of such performance is reasonably probable, ratably over the period over which we estimate that we will perform such performance obligations. Substantive at-risk milestone payments, which are based on achieving a specific performance milestone when performance of such milestone is contingent on performance by others or for which achievement can not be reasonably estimated or assured, are recognized as revenue when the milestone is achieved and the related payment is due, provided that there is no substantial future service obligation associated with the milestone. We do not recognize revenue in connection with license arrangements until payments are collected or due and reasonably assured of being collected. In addition, we do not recognize revenue in circumstances where the arrangement includes a refund provision until the refund condition is no longer applicable unless, in our judgment, the refund circumstances are within our operating control and unlikely to occur. Payments received in advance of being recognized as revenue are deferred.
In connection with feasibility studies, contract amounts which are not due until the customer accepts or verifies the research results are not recognized as revenue until customer acceptance, assuming collectability is reasonable assured.

We are recognizing collaboration revenue of $14.0 million associated with the initial license and performance-based payments under the Nycomed agreement based on an estimated recognition period of 66 months over which we are obligated to perform services supporting the agreement. This estimate was revised to 66 months in the third quarter of 2008. There was no change in the estimated development period during 2007. Estimation of this development period involves many assumptions, including estimates relating to completion of activities for which we are reliant on Nycomed and independent regulatory authorities to achieve. Our estimated development recognition period may change again if facts and circumstances change. Were the estimated development period to be extended, we may be required to record a reduction in cumulative revenue recognized in our statement of operations in the period in which the change in development period is determined.

Our agreement with Nycomed has been modified such that Nycomed has paid us $0.2 million for activities associated with creating a brand name for Imagify and related trademark activities and paid us $1.8 million to support the validation of the our commercial manufacturing facility for Imagify. These amounts were originally scheduled to be paid to us upon Nycomed’s filing for regulatory approval of Imagify in Europe. In September 2008, the arrangement with Nycomed was amended. This amendment removed a contingency associated with the $2.0 million of payments. As a result the $2.0 million has been included with $12 million and will be recognized over the 66 month development period utilizing the cumulative catch-up methodology. Payments received for current and potential HDDS and PDDS feasibility studies, which are offset by costs incurred for such studies, are recognized as revenue over the estimated performance period of each such study. A change in these estimates could result in a significant change to the amount of revenue recognized in future periods. In addition, if the Nycomed collaboration agreement is terminated for reasons other than certain non-performance by us, we would recognize the remainder of the payments we have received or otherwise expect to collect over the amortization period at the time of termination. We will not recognize revenue associated with the potential additional $56 million in milestone-based payments that may be earned under the Nycomed agreement until the underlying regulatory and sales milestones are achieved.

We entered into a license agreement with Cephalon, Inc., providing Cephalon with a license to our Hydrophobic Drug Delivery System (HDDS) for oncology applications, along with the rights to AI-850, our formulation of paclitaxel, in exchange for a cash payment of $10.0 million, paid upon the execution of the agreement. The term of the agreement extends until expiration of the last of the patents licensed under the agreement. During the term of the license we are obligated to support Cephalon activities in connection with AI-850. This support includes allowing access to our personnel for discussions relating to regulatory, scientific and medical technology and allow access to any records that may be required in connection with any regulatory filings or submissions. The Chairman, founder and CEO of Cephalon is also the current Presiding Director of the Board of Directors of the Company. Martyn Greenacre is also a member of the Board of Directors of both the Company and Cephalon. We recorded this payment in deferred revenue at September 30, 2008, and are recognizing it as income ratably over the remaining estimated useful life of the patents, or approximately 13 years.

Property and Equipment. Property and equipment are recorded at cost and depreciated over their estimated useful lives of three to five years using the straight-line method. The majority of our equipment is related to our ongoing research and development activities, including equipment which, subject to regulatory approvals, we intend to use for commercial manufacture of Imagify. We consider that this equipment is placed in service when operation of the equipment is started-up and begin depreciating the equipment at this time. The equipment in our commercial manufacturing facility is currently undergoing research and development related activities that result in wear and tear on the equipment including ongoing calibration and testing.

Leasehold improvements and equipment under capital leases are recorded at cost. We depreciate leasehold improvements and equipment under capital leases over the lesser of their useful lives or the remainder of their respective lease terms. We began depreciation of leasehold improvements at our Tewksbury facility in October 2005 upon receipt of an occupancy permit and taking occupancy of the facility. Our leasehold improvements costs on this facility approximate $30.7 million and are being depreciated ratably over the remaining term of our present lease, the initial term of which is scheduled to expire in April 2010. We believe that the use of the initial term of the lease for the depreciation period, rather than assuming that the lease term is renewed, is appropriate given the inherent uncertainties with a product such as Imagify, which has completed its phase 3 clinical trials but still requires regulatory approvals before it can be marketed. The Risk Factors included under Section 1A of this document discuss the uncertainties associated with Imagify.

Accrued Expenses. As part of the process of preparing consolidated financial statements we are required to estimate accrued expenses. This process involves identifying services which have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our consolidated financial statements.
Examples of estimated expenses for which we accrue include professional service fees, such as lawyers and accountants, and contract service fees such as amounts paid to clinical monitors, data management organizations and investigators in conjunction with clinical trials, and fees paid to consultants used in the qualification of our commercial manufacturing facility for Imagify. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs which have begun to be incurred or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the estimate of cost of such services at a cutoff date are often judgmental. We make these judgments based upon the facts and circumstances known to us in accordance with accounting principles generally accepted in the United States of America.

Stock-Based Compensation and Other Equity Instruments. We account for stock-based compensation in accordance with the fair value recognition provisions of SFAS 123R, Share-Based Payment. Under SFAS 123R, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the appropriate vesting period. Determining the fair value of stock-based awards at the grant date requires judgment, including estimating the expected term of stock options, the expected volatility of our stock and expected dividends. In addition, judgment is required in estimating the amount of stock-based awards that are expected to be forfeited. If actual results differ significantly from these estimates or different key assumptions were used, it could have a material effect on our Consolidated Financial Statements. See Note 3 of the Notes to the Consolidated Financial Statements for additional information regarding stock-based compensation expense.

Accounting for equity instruments granted or sold by us under APB No. 14, APB No. 25, SFAS 123 and EITF No. 96-18, such as the warrants issued in conjunction with certain sales of common stock, requires fair value estimates of the equity instrument granted or sold. If our estimates of the fair value of these equity instruments are too high or too low, it would have the effect of overstating or understating expenses. When equity instruments are granted or sold in exchange for the receipt of goods or services and the value of those goods or services can be readily estimated, we use the value of such goods or services to determine the fair value of the equity instruments. When equity instruments are granted or sold in exchange for the receipt of goods or services and the value of those goods or services cannot be readily estimated, as is true in connection with most stock options and warrants granted to employees or non-employees, we estimated the fair value of the equity instruments based upon consideration of factors which we deemed to be relevant at the time using cost, market and/or income approaches to such valuations.

The fair values of all stock option grants issued were determined using a Black-Scholes model in which we are required to make assumptions for the risk-free interest rate, the expected volatility of the underlying stock, forfeiture rates and expected life of option grants. The risk-free rates are the weighted average of the yield rates on 5-year U.S. Treasury notes on the dates of the stock option grants. We used the historical volatility of our market-traded stock for the expected volatility assumption. Forfeiture rates are calculated based on actual historical forfeitures. The expected life of employee stock options represents the weighted-average period the stock options are estimated to remain outstanding. The expected life of employee stock options is, in part, a function of the options’ remaining contractual life and the extent to which the option is in-the-money (i.e., the average stock price during the period is above the strike price of the stock option). We estimate that, based on these variables, options are likely on average to be exercised in approximately 5 years from the date of grant.

Derivative Liabilities. The terms of our February 2005 convertible preferred stock offering and our March 2005 MassDevelopment loan agreement contain features considered to be embedded derivatives which are recorded at estimated fair value in accordance with SFAS 133. The estimation of this fair value includes various assumptions and estimates, including assumptions and estimates of risk free interest rates, stock price volatility and the timing of future preferred stock conversions. Changes in these estimates and assumptions can increase or decrease the value of this derivative liability. The unrealized gain or loss of the derivative financial instrument is included in our statement of operations. The convertible preferred stock terms include a dividend make-whole payment provision, which has been initially recorded at its estimated fair value. This derivative liability is reduced upon conversion of the preferred stock as well as dividends declared by our board of directors, if any. The MassDevelopment loan agreement includes a provision for a retroactive interest rate increase in the event that we achieve certain defined positive operating cash flows. The initial fair value of the MassDevelopment loan derivative is being amortized over a term beginning with the loan agreement effective date and ending with the estimated payment date of the retroactive interest. The fair value of both derivative liabilities are re-measured at each reporting period.

Income Taxes. Deferred tax liabilities and assets are provided for differences between the book and tax bases of existing assets and liabilities and tax loss carryforwards and credits, using tax rates expected to be in effect in the years in which differences are expected to reverse. Valuation allowances are provided to the extent realization of tax assets is not considered likely.

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On January 1, 2007 we adopted FASB Interpretation No. 48 (“FIN 48”), Accounting for Uncertainty in Income Taxes — an Interpretation of FASB Statement No. 109, which clarifies the accounting for uncertainty in income tax positions. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

There were no unrecognized tax benefits as of the date of adoption January 1, 2007. As a result of the implementation of FIN 48, we did not recognize an increase in the liability for unrecognized tax benefits. There are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate. The Company’s practice is to recognize interest and/or penalties related to income tax matters in income tax expense. We had no accrual for interest or penalties on our balance sheets at December 31, 2007 and at September 30, 2008, and has not recognized interest and/or penalties in the statement of operations for the period ended December 31, 2008.

Recently Issued Accounting Pronouncements

In September 2006, the FASB issued SFAS (FAS) No. 157, Fair Value Measurements (“SFAS No. 157”), which is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The purpose of FAS No. 157 is to clarify and set forth consistent rules for defining fair value, establishing a framework for measuring fair value in generally accepted accounting principles and expanding disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements where those accounting pronouncements have determined that fair value is the relevant measurement attribute. FAS No. 157 does not require any new fair value measurements, but for some entities the application of FAS No. 157 could change current practice. Except as described below, we have adopted SFAS No. 157 on January 1, 2008. The adoption of SFAS No. 157 did not have a material impact on our financial statements or disclosures.

In February 2008, FASB issued FASB FSP FAS 157-2, Effective Date of FASB Statement No. 157 (FSP 157-2). FSP 157-2 will provide a one-year deferral of the effective date of SFAS No. 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in financial statements at fair value at least annually. For non-financial assets and non-financial liabilities subject to the deferral, SFAS No. 157 will be effective in fiscal years beginning after November 15, 2008 and in interim periods within those fiscal years. We are currently evaluating the impact that applying FAS No. 157 to nonfinancial assets and liabilities will have on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities, which is effective as of the beginning of an entity’s first fiscal year beginning after November 15, 2007. This statement allows the measurement at fair value of financial instruments and certain other items that are currently not required to be measured at fair value. The objective of SFAS No. 159 is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. The fair value option established by this Statement permits the measurement of eligible items at fair value at specified election dates, with unrealized gains and losses on the items for which the fair value option has been elected reported in earnings at each subsequent reporting date. SFAS No. 159 was effective for us in the first quarter of 2008. The adoption of SFAS No. 159 did not have an impact on our financial statements or condition as we did not elect to use fair value measurements on any assets or liabilities under this statement and have not subsequently elected to carry any assets or liabilities at fair value.

In June 2007, the Emerging Issues Task Force issued EITF 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities, which is effective as of the beginning of an entity’s first fiscal year beginning after December 15, 2007. This abstract discusses the treatment of the nonrefundable portion of advance payments made pursuant to an executory contractual arrangement for future research and development activities. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. We adopted this statement as of January 1, 2008 and concluded it has no effect on our consolidated financial statements.
In March 2008, the FASB issued SFAS No. 161, an amendment of SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, which is effective as of the beginning of an entity’s first fiscal year beginning after November 15, 2008. This Statement changes the disclosure requirements for derivative instruments and hedging activities, requiring enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under Statement 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity’s financial position, financial performance, and cash flows. We are assessing the impact, if any, of this pronouncement on our consolidated financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We have not used derivative financial instruments for speculative or trading purposes. However, we are exposed to market risk related to changes in interest rates. Our current policy is to maintain an investment portfolio consisting mainly of U.S. money market and government-grade securities, directly or through managed funds, with original maturity dates of 90 days or less when purchased. Our cash is deposited in and invested through highly rated financial institutions in North America. Our cash equivalents are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10% from levels at September 30, 2008, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. Since our investment portfolio consists of short-term, highly liquid investments, including money market accounts, with original maturity dates of 90 days or less when purchased, we do not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. Our equipment loans and capital leases are not subject to interest rate fluctuations because the interest rates are fixed at the time of borrowing.

Effects of Inflation

Our assets are primarily monetary, consisting of cash, cash equivalents and short-term investments. Because of their liquidity, these assets are not directly affected by inflation. We also believe that we have intangible assets in the value of our technology. In accordance with generally accepted accounting principles, we have not capitalized the value of this intellectual property on our consolidated balance sheet. Due to the nature of this intellectual property, we believe that these intangible assets are not affected by inflation. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(b) promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the evaluation date, our disclosure controls and procedures were effective in ensuring that material information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms, including ensuring that such material 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.

Changes in Internal Control Over Financial Reporting

During the period covered by this report, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.
ITEM 1. LEGAL PROCEEDINGS

None

ITEM 1A. RISK FACTORS

Certain Factors Which May Affect Future Results

Our operating results and financial condition have varied in the past and may in the future vary significantly depending on a number of factors. Except for the historical information in this report, the matters contained in this report include forward-looking statements that involve risks and uncertainties. The following factors, among others, could cause actual results to differ materially from those contained in forward-looking statements made in this report and presented elsewhere by management from time to time. Such factors, among others, may have a material adverse effect upon our business, results of operations and financial condition.

In Part I, Item 1A (“Risk Factors”) of our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, which was filed with the Securities and Exchange Commission on March 17, 2008, we describe risk factors related to the Company. For convenience, our updated risk factors are included below in this Item 1A. Other than the risk factors titled:

- Based on our current capital resources, including the proceeds from the Cephalon transaction received on November 3, 2008 and based on our current operating plans, we will require significant additional capital to fund our operations through and beyond the second quarter of 2009. There is substantial doubt as to our ability to continue as a going concern.
- We need to allocate significant amounts of our available capital resources to make payments on our outstanding indebtedness and equipment lease obligations, our patent transfer agreement with Bayer Schering Pharma AG, our patent license agreement with GE, our patent license agreement with Bracco and as dividends on our 6.5% convertible exchangeable preferred stock, which in turn could reduce our financial flexibility and ability to fund other activities.
- Failure to obtain regulatory approvals for our product candidates under development, in particular our lead product candidate Imagify, for which we missed endpoints in each of our pivotal trials, would have a material adverse effect on our business.
- If Cephalon converts its convertible promissory note into the right to enter into an exclusive license for Imagify, we will have no other product candidates in active clinical development.
- In connection with our November 2008 transaction with Cephalon we granted Cephalon a security interest in substantially all of our assets, including our intellectual property, which could hinder our ability to secure additional debt financing.
- Under the terms of our November 2008 agreement with Cephalon, we can not undertake certain specified corporate actions without the consent of Cephalon, which could frustrate our ability to raise equity or debt or enter into future collaboration agreements, among other things.
- FDA has required warning labels be added to product labeling for certain contrast agents as a result of serious adverse events and, if approved, our Imagify product candidate may require similar labeling.
- We may need to enroll more patients in future clinical trials, and any such additional enrollment would require additional expenditures, which may be material, and would likely result in a delay of ultimate approval of the for Imagify.
- We have never manufactured any of our product candidates in commercial quantities, and if we fail to develop an effective manufacturing capability for our products, including our lead product candidate Imagify, we may be unable to commercialize these products.
- We may not be able to manufacture our products in commercial quantities, which would prevent us from marketing our products.
- Materials necessary to manufacture our products may not be available, which may delay our development and commercialization activities.
- Competition in the pharmaceutical industry is intense, and if we fail to compete effectively our financial results will suffer.
- Our products involve the use of hazardous materials, and as a result we are exposed to potential liability claims and to costs associated with complying with laws regulating hazardous waste.
- Our common stock may be delisted from the Nasdaq Capital Market, which could negatively impact the price of our common stock and our ability to access the capital markets.
If Cephalon elects to convert its convertible promissory into shares of our common stock, it will likely result in immediate and substantial dilution to our stockholders and potentially give Cephalon control over stockholder votes.
If Cephalon elects to convert its convertible promissory into shares of our common stock, it will have the right to proportional representation on our board of directors, which would provide Cephalon with an opportunity to exert significant control over the strategic direction of Acusphere.

If shares under our universal shelf registration statement are issued, then the price of our securities may be negatively affected.

Our common stock is junior to our preferred stock with respect to the right to receive payments in the event of a dissolution, liquidation or winding up of Acusphere.

Future sales of common stock by our existing stockholders may cause our stock price to fall.

The terms of our outstanding shares of preferred stock may restrict our ability to raise additional capital or hamper or prevent an acquisition of us.

Under some circumstances, the holders of our outstanding shares of preferred stock may be entitled to elect some of the directors of Acusphere.

In connection with our November 2008 transaction with Cephalon we waived Section 203 of the Delaware General Corporation Law and agree to seek shareholder approval of certain provisions of our certificate of incorporation, which may make it more difficult to discourage an acquisition of Acusphere by Cephalon or others.

There have been no material changes in our risk factors from those disclosed in Part I. Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

Risks Related to Our Company

Based on our current capital resources, including the proceeds from the Cephalon transaction received on November 3, 2008 and based on our current operating plans, we will require significant additional capital to fund our operations through and beyond the second quarter of 2009. There is substantial doubt as to our ability to continue as a going concern.

We are focused on product development and we have not generated any revenue from commercial sales of our products to date. We have incurred losses each year of our operations. For the nine months ended September 30, 2008, we had a net loss available to
holders of common stock of $36.3 million. At September 30, 2008 we had an accumulated deficit of $369.7 million. We expect our research and development, general and administrative and sales and marketing expenses will increase over the next several years.

We expect to continue to incur losses and capital expenditures for the foreseeable future. We also anticipate cash outflow from debt repayment and payment of other obligations, including dividends payable on our outstanding shares of 6.5% convertible exchangeable preferred stock. Proceeds from the Cephalon transaction received on November 3, 2008 and based on our operating plans, we will require significant additional capital to fund our operations through and beyond the second quarter of 2009, including developing products, conducting clinical trials, achieving regulatory approvals, qualifying commercial manufacturing space and, subject to regulatory approval, commercially launching Imagify, or other product candidates under development or future product candidates. We may raise this additional capital through public or private sales of equity, or from borrowings, or from strategic partners.

As a result of our limited capital resources, we have elected and may continue to elect to delay the funding of certain development activities which would result in a delay in the approval and/or commercialization of Imagify. Any such delay in approval and/or commercialization of Imagify would have a material adverse impact on our business and would likely have a material adverse effect on the market price of our common stock. To address our capital needs, we may elect to raise funds through public or private sales of equity or from borrowings or from strategic partners. Additional equity financing, if available, will be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate our business; and strategic partnerships, if available, may result in royalties or other terms which reduce our economic potential from products under development. In addition, third parties may attempt to acquire us at valuations our board of directors or stockholders may not find attractive. Since our present capital resources are not sufficient to fund our planned operations for a twelve month period as of the date of this Quarterly Report on Form 10-Q, our current financial resources raise substantial doubt about our ability to continue as a going concern.

We cannot assure you that we can obtain additional funding on reasonable terms, or at all. If we raise additional funds by issuing equity securities, our stock price may decline, our existing stockholders will experience significant dilution, and the newly issued securities may have rights superior to those of our common stock. If we raise additional funds by issuing debt, we may be subject to limitations on our operations and such debt may have rights senior to the debentures, if issued. If we cannot obtain adequate funds, we may:

- terminate or delay clinical trials for one or more of our product candidates;
- delay our establishment of sales, marketing and/or manufacturing capabilities;
- relinquish rights to our technologies or product candidates;
- terminate or delay qualification of our commercial manufacturing facility; and/or
- terminate or delay development of one or more of our product candidates, including Imagify, and discontinue operations of all or a portion of our operations.

We need to allocate significant amounts of our available capital resources to make payments on our outstanding indebtedness and equipment lease obligations, our patent transfer agreement with Bayer Schering Pharma AG, our patent license agreement with GE, our patent license agreement with Bracco and as dividends on our 6.5% convertible exchangeable preferred stock, which in turn could reduce our financial flexibility and ability to fund other activities.

As of November 1, 2008, we had approximately $14.6 million in aggregate principal indebtedness outstanding related to capital lease obligations, notes payable, accrued dividends and other long-term obligations. As of November 6, 2008, we had outstanding 310,000 shares of our 6.5% convertible exchangeable preferred stock, which shares accrue cumulative cash dividends at the annual rate of $3.25 per share, payable quarterly on the first day of March, June, September, and December. These payments will:

- reduce the availability of our capital to fund our clinical trials for Imagify, the qualification of our commercial manufacturing space in Tewksbury, Massachusetts and for working capital and other general corporate purposes and may require us, in order to meet these obligations, to delay or reduce expenditures or forego business opportunities; and
- potentially impair our ability to obtain additional financing.

To address our capital needs, we may elect to raise funds through public or private sales of equity or from borrowings or from strategic partners. Additional equity financing, if available, will be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; and strategic partnerships, if available, may result in royalties or other terms which reduce our economic potential from products under development.
Failure to obtain regulatory approvals for our product candidates under development, in particular our lead product candidate Imagify, for which we missed endpoints in each of our pivotal trials, would have a material adverse effect on our business.

We must receive regulatory approval of each of our product candidates before we can commercialize or sell that product candidate. The pre-clinical laboratory testing, formulation development, manufacturing and clinical trials of any product candidates we develop independently or in collaboration with third parties, as well as the distribution and marketing of these product candidates, are regulated by numerous federal, state and local governmental authorities in the United States, principally FDA, and by similar agencies in other countries. The development and regulatory approval process takes many years, requires the expenditure of substantial resources, is uncertain and subject to delays, and could thus delay our receipt of revenues, if any, from any of our product candidates.

The data obtained from clinical and pre-clinical activities are subject to varying interpretations that could delay, limit or prevent regulatory agency approval. In particular, we can not assure you that our Imagify clinical results will successfully address FDA requirements sufficiently for us to obtain regulatory approval. No product can receive FDA approval unless human clinical trials show both safety and efficacy for each target indication in accordance with FDA standards. FDA analysis of results include both quantitative and qualitative analysis. In both our RAMP-1 and RAMP-2 clinical trial results, we achieved the principal primary endpoint of accuracy but failed to achieve one of the two component primary endpoints in each trial (sensitivity in RAMP-1 and specificity in RAMP-2). The FDA may look at these trials separately rather than in their totality and may not approve Imagify based upon these missed endpoints. We cannot predict whether FDA will approve Imagify based upon the available results or whether FDA will seek additional data as a condition to approval or whether they will approve Imagify at all. FDA has announced that the NDA for Imagify will be discussed by the Cardiovascular and Renal Drugs Advisory Committee at their meeting on December 10th, 2008. We cannot predict the outcome of these discussions, the advice that may be given to FDA or the impact on approvability of Imagify or the timing thereof.

Our RAMP-1 and RAMP-2 clinical trial results are based upon our statistical analysis plans for those trials. These statistical analysis plans, including calculations of statistical significance, were created based on a variety of factors, including feedback from our discussions with FDA, the input of our regulatory consultants and our own knowledge and past experience in these and similar matters. We anticipate that the FDA will evaluate the quality and independence of the manner in which our Imagify clinical trials were conducted. In recent years, other companies seeking approval for their contrast agents have encountered difficulties convincing FDA that the comparative or truth standards that they used in their clinical trials met acceptable levels of quality, consistency or other standards acceptable to the FDA. In such cases, these issues were reported to be contributing factors in the failure of such product candidates to be approved. If the FDA, upon review, has concern about the manner in which our RAMP-1 or RAMP-2 trials were conducted, or has concerns about the results of the nuclear stress tests or coronary angiography used as a comparator and truth standard in these trials, this could delay or prevent FDA approval of Imagify based upon our current trial results. There can be no assurance that FDA will accept our statistical analysis without modification. How, when, or if such matters are resolved may affect whether Imagify is approved for the indication that we are seeking, the timing of such approval, or whether Imagify is approved at all. In addition, in conjunction with approving products, it is common for regulatory agencies to impose limits on how such products can be used and marketed. We anticipate that if and when Imagify and other product candidates are approved that the initial use and marketing of these products may be limited at least until such time as we conduct additional clinical studies or information otherwise becomes available to address the underlying reasons for such limitations.

We may encounter delays or rejections based on changes in regulatory agency policies or personnel during the period in which we develop a drug or the period required for review of any application for regulatory agency approval of a particular compound. Our continuing efforts to comply with these changes could lead to delays or rejections of our clinical trials. We also may encounter delays in the event we are unable to produce clinical trial material in sufficient quantities and of sufficient quality to meet the schedule for our planned clinical trials. In addition, we rely on a number of third parties, such as clinical research organizations, to help support the clinical trials by performing independent clinical monitoring, data acquisition and data evaluations. Any failure on the part of these third parties could delay the regulatory approval process.

Failure to obtain regulatory approval or any delay or setback in obtaining regulatory agency approvals could:

- adversely affect our ability to market any drugs we develop independently or with collaborative partners;
- impose additional costs and diminish any competitive advantages that we may attain; or
- adversely affect our ability to generate royalties.
Failure to obtain approval for our lead product candidate, Imagify, or delay in such approval, would delay our receipt of product revenues and would have a material adverse affect our business, financial condition and results of operations. Our stock price would also be materially adversely affected.

**If Cephalon converts its convertible promissory note into the right to enter into an exclusive license for Imagify, we will have no other product candidates in active clinical development.**

If Cephalon converts the its convertible promissory note into the right to enter into an exclusive license for Imagify, we will no longer have any right to commercialize Imagify and will thereafter only be entitled to receive milestone and royalty payments from our licensees in connection with the sale of Imagify. We currently have no product candidates in active clinical development. Any future product candidate we may develop would require many years of pre-clinical and clinical development, regulatory approval and substantial additional resources, before we could commercialize that product candidate.

**In connection with our November 2008 transaction with Cephalon we granted Cephalon a security interest in substantially all of our assets, including our intellectual property, which could hinder our ability to secure additional debt financing.**

In connection with our November 2008 transaction with Cephalon, we issued Cephalon a $15 million senior secured convertible note and granted Cephalon a security interest in substantially all of our assets, including our intellectual property, to secure our obligations under the convertible note. The Cephalon convertible note is subject to acceleration and an increased interest rate upon the happening of customary events of default, including the failure to make timely payments of principal and interest. Cephalon would have the right to realize on these secured assets to satisfy amounts owed under the note in an event of default. If Cephalon were to realize on these secured assets, especially our intellectual property rights, it would have a material adverse effect on our business.

In addition, because we have now granted a security interest in all of our assets to Cephalon and other lenders, it may become more difficult for us to raise additional debt to fund our continued operations.

**Under the terms of our November 2008 agreement with Cephalon, we can not undertake certain specified corporate actions without the consent of Cephalon, which could frustrate our ability to raise equity or debt or enter into future collaboration agreements, among other things.**

Pursuant to the terms of our note purchase agreement with Cephalon, we are not permitted to undertake certain specified corporate actions, such as issue additional equity securities or securities convertible into equity securities, enter into a material joint venture or partnership with a third party, incur additional indebtedness, enter into the sale of the Company, or amend our certificate of incorporation or bylaws, for so long as the Cephalon convertible note remains outstanding or Cephalon holds at least 25% or more of our outstanding voting securities, which period we refer to as the restricted period, without the prior consent of Cephalon. Cephalon’s control over our ability to enter into certain of these corporate actions may frustrate our ability to issue additional equity or debt securities or enter into future collaborations related to our products.

**Adverse events are likely to be encountered in our clinical trials and these events could delay, limit or prevent regulatory approval.**

Many of the patients in our Imagify clinical trials have coronary artery disease. As part of our Imagify clinical trials, patients are exposed to potential safety risks associated with a stress test, including risks associated with a pharmacological stressor, and Imagify. Given the nature of the Imagify clinical trials, including the cumulative administration of Imagify to larger numbers of at-risk patients and administering Imagify to patients with coexisting disease, adverse events are expected to be encountered during any future clinical trials. Adverse events are also likely to be encountered in clinical trials for our other products, which clinical trials may also include at-risk patients. When significant adverse events are detected and these events are attributable to our products, such events could delay, limit or prevent regulatory agency approval.

**FDA has required warning labels be added to product labeling for certain contrast agents as a result of serious adverse events and, if approved, our Imagify product candidate may require similar labeling.**

FDA has required warning labels to be added to product labeling for certain ultrasound contrast agents which are approved for use in clinically unstable and acutely ill patients. These FDA-approved agents, Optison, marketed by GE Healthcare and Definity, marketed by Lantheus Medical Imaging, are injected into patients prior to a cardiac ultrasound to improve visibility of the image. While we believe that Imagify is structurally different from these commercially-available ultrasound contrast agents, we cannot assure you that,
if approved, Imagify will not be required to carry a similar warning. As a result, the potential market size may be significantly smaller.

**Our collaborative partners may not obtain regulatory approvals in other countries, which may have an adverse effect on our business.**

We cannot be certain that we or our partners will obtain any regulatory approvals in other countries and the failure to obtain these approvals would have a material adverse affect on our business, financial condition and results of operations. In order to market our products outside of the United States, we and our current, and potential future, collaborative partners must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. The approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks associated with obtaining FDA approval detailed above. Approval by FDA does not ensure approval by the regulatory authorities of other countries. In addition, many countries outside the United States require a separate review process prior to marketing to determine whether their national health insurance schemes will pay for newly approved products, as well as the price which may be charged for a product.

**We may need to enroll more patients in future clinical trials, and any such additional enrollment would require additional expenditures, which may be material, and would likely result in a delay of ultimate approval of the for Imagify.**

If discussions with FDA lead us to conclude that further clinical trials of Imagify are required to achieve NDA approval, such trials may affect the timing of such ultimate approval and we would incur significant additional costs. We cannot assure that the performance of additional trials would lead ultimately to NDA approval. Moreover, we currently do not possess sufficient inventory of Imagify to conduct any such trial, and would need to contract for the manufacture of such material. We may not be able to obtain sufficient quantity of such material in a timely fashion or on commercially reasonable terms, or at all. Our inability to conduct additional clinical trials for Imagify in a timely fashion, or at all, resulting from of our inability to manufacture or obtain clinical trial materials would have material adverse effect on our business.

**If we cannot raise additional capital on acceptable terms, we may be unable to complete planned clinical trials, obtain regulatory approvals or commercialize our product candidates.**

We will require substantial future capital in order to continue to conduct the research and development, clinical and regulatory activities necessary to bring our product candidates to market and to establish commercial manufacturing, marketing and sales capabilities. Our future capital requirements will depend on many factors, including the:

- progress of pre-clinical development and laboratory testing and clinical trials;
- timing of construction and size to which we expand our manufacturing capabilities;
- time and costs involved in obtaining regulatory approvals;
- number of product candidates we pursue;
- costs involved in filing and prosecuting patent applications and enforcing or defending patent claims; and
- establishment of selected strategic alliances and activities required for product commercialization.

We may seek additional funding through strategic collaborations or through private or public sales of our securities or by licensing all or a portion of our technology. This funding will significantly dilute existing stockholders or may limit our rights to our technology. Any of these could have a material adverse effect on our business, financial condition and results of operations. Our stock price could also be materially adversely affected.

**Our products, if approved, may fail to achieve market acceptance.**

There can be no assurance that any products we successfully develop, if approved for marketing, will achieve market acceptance or generate significant revenues. Each of our product candidates is intended to replace or alter existing therapies or procedures, and hospitals, physicians or patients may conclude that these products are less safe or effective or otherwise less attractive than these existing therapies or procedures. For example, our lead product candidate, Imagify, is a cardiovascular drug for use in ultrasound imaging procedures which will compete with existing nuclear imaging and cardiac ultrasound. Hospitals, physicians or patients may prefer these existing procedures to Imagify perfusion stress ultrasound imaging. If our products do not receive market acceptance for any reason, it would adversely affect our business, financial condition and results of operations. In such event, we may elect to
conduct additional clinical trials designed to demonstrate the effectiveness of Imagify in circumstances not studied in our Phase 3 clinical trials. Any such studies will likely be expensive and time consuming. Further, our competitors may develop new technologies or products that are more effective or less costly, or that seem more cost-effective, than our products. We can give no assurance that hospitals, physicians, patients or the medical community in general will accept and use any products that we may develop.

**We have never manufactured any of our product candidates in commercial quantities, and if we fail to develop an effective manufacturing capability for our products, including our lead product candidate Imagify, we may be unable to commercialize these products.**

We have no experience in manufacturing our products for commercial use and limited experience in designing equipment for the manufacture of our products. We are working to qualify operations at a commercial manufacturing facility in Tewksbury, Massachusetts and to demonstrate that we can produce Imagify at a commercial manufacturing scale, and subject to required regulatory approvals, we intend to manufacture Imagify in this facility for commercial use. We can not assure you that we will be able to obtain the necessary regulatory approvals for such commercial manufacture, at all or in a timely or economical manner. Our intention to manufacture Imagify or other products exposes us to the following risks, any of which could delay or prevent the approval of our products by FDA or corresponding state and foreign agencies, or the commercialization of our products, or result in higher costs or inability to meet demand for Imagify leading to potential revenue loss, and any of which would have a material adverse impact on our business, financial condition and results of operations.

- Manufacturers are obliged to manufacture in highly controlled environments and to operate in accordance with FDA and international mandated current good manufacturing practices, or cGMPs. For our clinical trials we have relied on contract manufacturers for such facilities and cGMP compliance. Creation and qualification of a commercial manufacturing environment requires significant expertise and capital resources, including the development of advanced manufacturing techniques and process controls and is subject to local and state planning approvals. Manufacturers of pharmaceutical products often encounter difficulties in constructing and qualifying new manufacturing facilities and in production, especially in scaling-up initial production. A failure to establish and follow cGMPs and to document adherence to such practices may lead to significant delays in the availability of material for commercial production for Imagify and may delay or prevent filing or approval of marketing applications for our products or the ability to continue to manufacture the products. Certain of these delays would further require us to continue to operate this facility and incur related costs.

- Manufacture of our product candidates, in preparation for commercial production, will each initially require and rely on a single commercial manufacturing site, directly or through a contract manufacturer, without the backup of a second site that is qualified for commercial manufacture of the product. Qualification of another manufacturing site can be expensive and time consuming. Prior to using product from a new manufacturing site, we must demonstrate to FDA and corresponding state and foreign agencies that the specifications for the product are consistent with the specifications for the product as it was manufactured at a prior qualified site or we must clinically or otherwise demonstrate that the safety and efficacy of the product produced in the new manufacturing site is consistent with the product as it was manufactured at the prior site. Demonstrating such consistency may be difficult, expensive or time consuming. In addition, before we would be able to produce product for commercial use at a new facility, it will have to undergo a pre-approval inspection by FDA and corresponding state and foreign agencies. Once approved, drug manufacturers are subject to ongoing periodic unannounced inspection by FDA and corresponding state and foreign agencies to ensure strict compliance with cGMPs, other government regulations and corresponding foreign standards. Failure to maintain compliance with cGMP or with safety or environmental regulations could result in penalties, product recalls or restrictions on the use of the manufacturing site.

We have a single manufacturing facility. This facility and the manufacturing equipment we use to produce Imagify would be difficult to replace and could require substantial lead-time to repair or replace in the event of a regulatory, manufacturing, catastrophic event or similar problem. In such event, we would be forced to rely on third-party manufacturers and there would likely be substantial delay before we would be able to restart production. Although we possess insurance for damage to our property and the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses, including potential damage to our reputation, and may not continue to be available to us on acceptable terms, or at all. In addition, future growth may outpace our manufacturing capacity, in which event we would need to locate, obtain and build-out additional space. New or alternative facilities may not be available to us on acceptable terms. Even if we are able to identify such new or alternative facilities, we may incur additional costs and we may experience a disruption in the supply of our products until those facilities are available.
Failure to manufacture our products in commercial quantities or at commercially reasonable rates could damage our European partnership.

Under the terms of our collaboration agreement with Nycomed, we are responsible for the commercial manufacture of Imagify for marketing and sale by Nycomed in Europe. Failure to manufacture Imagify in a timely manner or on an economic basis, or in sufficient quantities, could jeopardize our relationship with Nycomed. We do not currently have a European sales force, nor do we have experience with regard to the commercialization, marketing, sale or distribution of pharmaceutical products in Europe, and we rely entirely on Nycomed for this expertise. Any termination of our relationship with Nycomed would have a material adverse impact on our business, financial condition and results of operations.

We may not be able to manufacture our products in commercial quantities, which would prevent us from marketing our products.

To date our product candidates have been manufactured in small quantities for pre-clinical and clinical trials. If any of these product candidates are approved by FDA or foreign regulatory authorities for commercial sale, we will need to manufacture them in larger quantities. For Imagify, we are seeking regulatory approval after we have demonstrated that we can manufacture Imagify at a larger batch scale than is being used for clinical trial materials. However, manufacturers often encounter difficulties in achieving volume production, quality control and quality assurance and we might not be able to manufacture sufficient quantities of drugs to meet our clinical schedules or to commercialize our products. We cannot assure you that we will be able to successfully increase the manufacturing capacity or manufacture at a larger batch scale, whether on our own or in collaboration with third party manufacturers, for any of our product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require certain additional validation studies, which FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply of that product candidate. Our product candidates require precise, high-quality manufacturing. Our failure to achieve and maintain these high manufacturing standards, including controlling the incidence of manufacturing errors and maintaining reliable product packaging for diverse environmental conditions, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business.

Our commercial manufacturing facility in Tewksbury, Massachusetts is designed to meet our estimated initial commercial demand for Imagify. The facility is being initially equipped to run one production line. In order to support greater production capacity, this production line is designed to support a larger lyophilizer (pharmaceutical freeze dryer which can be operated under sterile conditions) in addition to the one that has been initially installed. Purchasing, installing and qualifying manufacturing equipment, such as a lyophilizer, typically requires significant lead times and temporary discontinuation of production. Also in the future we may need to add additional production lines at the Tewksbury site or elsewhere to meet potential commercial demand for Imagify. We have made no commitment to such additions at this time. The cost of such additions can be significant. There can be no assurance that our capacity estimates will be achieved. Any such additions would increase our operating spending, increase our capital requirements and reduce our resources available for development activities.

We have removed our Imagify manufacturing equipment from the facilities of our third party contract manufacturer and currently have no facility within which to manufacture Imagify until the new commercial manufacturing facility is qualified or until other arrangements are made.

We have removed our Imagify manufacturing equipment from the facilities of a third-party contract manufacturer. Currently, we have no facility within which to manufacture Imagify until the new commercial manufacturing facility is qualified or until other arrangements are made. We have no existing inventory of Imagify on-hand and would need to produce, or contract with a third party for the production of additional material for future clinical trials. If we are not able to secure sufficient inventory of Imagify clinical trial material to perform clinical trials, our program could be adversely impacted or delayed. These delays could have a material adverse effect on our business, financial condition and results of operations.

If third-party manufacturers of our product candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials may be delayed and our costs may rise.

We may rely substantially on third-party contract manufacturers to supply, store and distribute our product candidates for our clinical trials and other development needs. Our reliance on these third-party manufacturers will expose us to the following risks, any of which could delay or prevent the completion of our clinical trials, the approval of our products by FDA, or the commercialization of our
products, result in higher costs, or deprive us of additional product candidates, and any of such effects would have a material adverse impact on our business, financial condition and results of operations.

- Contract manufacturers often encounter difficulties in achieving volume production, quality control and quality assurance, as well as shortages of qualified personnel. Accordingly, a manufacturer might not be able to manufacture sufficient quantities of drugs to meet our clinical schedules.

- Contract manufacturers are obliged to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs. A failure of these contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in the availability of material for clinical study and may delay or prevent filing or approval of marketing applications for our products.

- For production of clinical trial material for each of our current product candidates we will initially rely on a single manufacturer. Changing these or future manufacturers may be difficult and the number of potential manufacturers is limited. Changing manufacturers may require re-validation of the manufacturing processes and procedures in accordance with FDA-mandated cGMPs. Such re-validation may be costly and time-consuming. It may be difficult or impossible for us to find replacement manufacturers on acceptable terms quickly, or at all.

- Our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to produce, store and distribute our products successfully. Our manufacturing levels, while important to us, can represent relatively small fractions of the overall business of most qualified contract manufacturers. As a result, the contract manufacturers may not provide us with the attention that we need or may be unwilling to adapt to necessary changes in our manufacturing requirements.

Drug manufacturers are subject to ongoing periodic unannounced inspection by FDA and corresponding state and foreign agencies to ensure strict compliance with cGMPs, other government regulations and corresponding foreign standards. While we are obligated to audit the performance of third party contractors, we do not have control over our third-party manufacturers’ compliance with these regulations and standards. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

Materials necessary to manufacture our products may not be available, which may delay our development and commercialization activities.

Only a few facilities manufacture some of the raw materials necessary to manufacture our products. If we need to purchase a raw material that is in limited supply or becomes unavailable for our clinical trials, or for commercial distribution if we obtain marketing approval of a product candidate, we cannot assure you that suppliers would be able to sell us that raw material at the time we need it and on commercially reasonable terms. If we change suppliers for any of these materials or any of our suppliers experiences a shutdown or disruption in the facilities used to produce these materials, due to technical, regulatory or other problems, it could harm our ability to manufacture our products or receive regulatory approval.

We have no experience selling, marketing or distributing our products and no internal capability to do so.

If we receive regulatory approval to commence commercial sale of any product, we will face competition with respect to commercial sales, marketing and distribution. These are areas in which we have no experience. To market any of our products directly, we must develop a direct marketing and sales force with technical expertise and supporting distribution capability. Alternatively, we may engage a pharmaceutical or other healthcare company with an existing distribution system and direct sales force to assist us. There can be no assurance that we will successfully establish sales and distribution capabilities either on our own or in collaboration with third parties or gain market acceptance for our products. To the extent we have or will enter co-promotion or other licensing arrangements, any revenues we receive will depend on the efforts of third parties and there can be no assurance that our efforts will succeed.

Our potential product trade names may not be acceptable to FDA.

FDA reserves the right to approve product names prior to commercialization. We have proposed to FDA the tradename Imagify, as well as an alternative tradename, as a potential product trade name for our lead product. FDA has raised concerns regarding the name
Imagify which, if not resolved, could cause us to use the alternative name which FDA finds acceptable. Trade names changes could result in additional cost to us and could adversely affect our preparations for commercialization of this product which could, in turn, adversely affect our business, financial condition and results of operations.

Claims by other parties that we infringe or have misappropriated their proprietary technology may result in liability for damages, royalties, or other payments, or stop our development and commercialization efforts.

Competitors and other third parties may initiate patent litigation against us in the United States or in foreign countries based on existing patents or patents that may be granted in the future. Many of our competitors have obtained patents covering products and processes generally related to our products and processes, and they may assert these patents against us. Moreover, there can be no assurance that these competitors have not sought or will not seek additional patents that may cover aspects of our technology. As a result, there is a greater likelihood of a patent dispute than would be expected if our competitors were pursuing unrelated technologies.

While we conduct patent searches to determine whether the technologies used in our products infringe patents held by third parties, numerous patent applications are currently pending and may be filed in the future for technologies generally related to our technologies, including many patent applications that remain confidential after filing. Due to these factors and the inherent uncertainty in conducting patent searches, there can be no guarantee that we will not violate third-party patent rights that we have not yet identified.

We know of U.S. and foreign patents issued to third parties that relate to aspects of our product candidates. There may also be patent applications filed by these or other parties in the United States and various foreign jurisdictions that relate to some aspects of our product candidates, which, if issued, could subject us to infringement actions. In particular, we are aware of U.S. and foreign patents owned by third parties, including potential competitors, which arguably cover aspects of our Imagify contrast agent. We and several of these parties have been actively engaged in opposing the grant of European patents with claims that arguably cover aspects of our Imagify product. Parties may contest patents in Europe prior to contesting the counterpart patents in the United States because of procedural differences between European and U.S. patent laws as well as economic considerations.

The owners or licensees of these and other patents may file one or more infringement actions against us. In addition, a competitor may claim misappropriation of a trade secret by an employee hired from that competitor. Any such infringement or misappropriation action could cause us to incur substantial costs defending the lawsuit and could distract our management from our business, even if the allegations of infringement or misappropriation are unwarranted. A need to defend multiple actions or claims could have a disproportionately greater impact. In addition, either in response to or in anticipation of any such infringement or misappropriation claim, we may enter into commercial agreements with the owners or licensees of these rights. The terms of these commercial agreements may include substantial payments, including substantial royalty payments on revenues received by us in connection with the commercialization of our products. Payments under such agreements could increase our operating losses and reduce our resources available for development activities. Furthermore, a party making this type of claim could secure a judgment that requires us to pay substantial damages, which would increase our operating losses and reduce our resources available for development activities. A judgment could also include an injunction or other court order that could prevent us from making, using, selling, offering for sale or importing our products or prevent our customers from using our products. If a court determined or if we independently concluded that any of our products or manufacturing processes violated third-party proprietary rights, our clinical trials could be delayed and there can be no assurance that we would be able to reengineer the product or processes to avoid those rights, or to obtain a license under those rights on commercially reasonable terms, if at all.

If we are unable to protect our intellectual property rights, our competitors may develop and market products with similar features that may reduce demand for our products, and we may be prevented from establishing collaborative relationships on favorable terms.

The following factors are important to our success:

- receiving patent protection for our product candidates;
- maintaining our trade secrets;
- not infringing on the proprietary rights of others; and
- preventing others from infringing our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.
We try to protect our proprietary position by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. Because the patent position of pharmaceutical companies involves complex legal and factual questions, the issuance, scope and enforceability of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from others may not provide any protection against competitors. Our pending patent applications, those we may file in the future, or those we may license from third parties, may not result in patents being issued. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed. The laws of many foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality agreements with parties that have access to it, such as our corporate partners, collaborators, employees and consultants. Any of these parties may breach the agreements and disclose our confidential information or our competitors might learn of the information in some other way. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

We may become involved in lawsuits and administrative proceedings to protect, defend or enforce our patents that would be expensive and time consuming.

In order to protect or enforce our patent rights, we may initiate patent litigation against third parties in the United States or in foreign countries. In addition, we have been and continue to be subject to certain opposition proceedings conducted in patent and trademark offices challenging the validity of our patents and may become involved in future opposition proceedings. The defense of intellectual property rights, including patent rights through lawsuits, interference or opposition proceedings, and other legal and administrative proceedings can be costly and can divert our technical and management personnel from their normal responsibilities. Such costs increase our operating losses and reduce our resources available for development activities. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

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 and despite protective orders entered by the court, 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 materially adversely affect our business and financial results.

If we are unable to retain key personnel and hire additional qualified scientific, manufacturing, sales and marketing, and other personnel, we may not be able to successfully achieve our goals.

We depend on the principal members of our scientific and management staff. The loss of these principal members’ services might significantly delay or prevent the achievement of research, development or business objectives and could materially adversely affect our business, financial condition and results of operations. We do not maintain key person life insurance on any of these principal members, except for the CEO. We have entered into executive employment agreements, as amended, with key members of the management team that provide for compensation and other benefits in the event these persons are terminated other than for cause, including in connection with a “change of control” of Acusphere, or if they terminate their employment for good reason.

Our success depends, in large part, on our ability to attract and retain qualified scientific and management personnel such as these individuals. We face intense competition for such personnel and consultants. We cannot assure you that we will attract and retain qualified management and scientific personnel in the future.

Further, we expect that our potential expansion into areas and activities requiring additional expertise, such as further clinical trials, governmental approvals, commercial manufacturing and marketing, will place additional requirements on our management, operational and financial resources. We expect these demands will require an increase in management and scientific personnel and the development of additional expertise by existing management personnel. The failure to attract and retain such personnel or to develop such expertise could materially adversely affect prospects for our success.
We will establish collaborative relationships, and those relationships may expose us to a number of risks.

We will rely on a number of significant collaborative relationships with pharmaceutical or other healthcare companies for our manufacturing, research funding, clinical development and/or sales and marketing performance. Reliance on collaborative relationships poses a number of risks, including the following:

- we cannot effectively control whether our corporate partners will devote sufficient resources to our programs or product candidates;
- disputes may arise in the future with respect to the ownership of rights to technology developed with collaborators;
- disagreements with collaborators could delay or terminate the research and development, regulatory approval or commercialization of product candidates, or result in litigation or arbitration;
- corporate partners may have considerable discretion in electing whether to pursue the development of any additional product candidates and may pursue technologies or products either on their own or in collaboration with our competitors; and
- collaborators with marketing rights may choose to devote fewer resources to the marketing of our product candidates than they do to product candidates of their own development.

In July 2004, we entered into a collaboration, license and supply agreement with Nycomed in which we granted Nycomed rights to develop and market Imagify in Europe. There can be no assurance that the regulatory goals, sales targets and other objectives of this agreement will be achieved. Failure to achieve these goals, targets and objectives would result in our inability to receive license, milestone, royalty and other payments under this agreement, which would have a material adverse impact on our business, financial condition and results of operations including, under certain conditions, reduction of royalty rates, delays in regulatory approvals and product sales, penalties and termination of the agreement. Under certain provisions of this collaboration agreement, if we fail in any material respect to use all commercially reasonable efforts to carry out referenced obligations under the agreement, we would be obligated to pay Nycomed liquidated damages of up to $12 million. Although we plan to carry out all of these obligations, which we believe are in our control, there can be no assurance that termination of this agreement will not occur or that such termination would not result in us incurring liquidated damages of up to $12 million.

Given these risks, our current and future collaborative efforts may not be successful. Failure of these efforts could delay our product development or impair commercialization of our products, and could have a material adverse effect on our business, financial condition and results of operations.

**Competition in the pharmaceutical industry is intense, and if we fail to compete effectively our financial results will suffer.**

We engage in a business characterized by extensive research efforts, rapid developments and intense competition. We cannot assure you that our products will compete successfully or that research and development by others will not render our products obsolete or uneconomical. Our failure to compete effectively would materially adversely affect our business, financial condition and results of operations. We expect that successful competition will depend, among other things, on product efficacy, safety, reliability, availability, timing and scope of regulatory approval and price. Specifically, we expect important factors will include the relative speed with which we can develop products, complete the clinical, development and laboratory testing and regulatory approval processes and supply commercial quantities of the product to the market.

We expect competition to increase as technological advances are made and commercial applications broaden. In commercializing our initial product candidates and any additional products we develop using our HDDS and PDDS technologies, we will face substantial competition from large pharmaceutical, biotechnology and other companies, universities and research institutions.

- Imagify, our cardiovascular drug and lead product candidate, if approved for marketing and sale, will compete with nuclear stress tests, the current standard of care in myocardial perfusion imaging. Nuclear imaging agents that are approved for use in myocardial perfusion imaging include products marketed by GE Healthcare and Lantheus Medical Imaging. In 2005, the reimbursement rate of a nuclear stress test was approximately $800 per procedure. In addition, GE Healthcare and Lantheus Medical Imaging have developed and marketed ultrasound contrast agents that have been used for Left Venticular Opacification, or LVO, and Endocardial Border Delineation, or EBD, in patients with suboptimal images. No ultrasound contrast agent has been approved by FDA for use in myocardial perfusion imaging using cardiac stress ultrasound. In addition, some companies have ultrasound contrast agents that are FDA approved for resting cardiac ultrasound evaluation of LVO and EBD in patients with suboptimal images or are in development. In the future, these companies may seek to broaden their indications to include myocardial perfusion assessment with cardiac stress ultrasound. These FDA-approved agents include Optison, which is marketed
by GE Healthcare and Definity, which is marketed by Lantheus Medical Imaging. SonoVue is an ultrasound contrast agent marketed in Europe by Bracco for LVO, EBD and radiology applications.

- **AI-850** (our reformulation of paclitaxel) or a reformulation of AI-850, if approved for marketing and sale, will also face intense competition. We are aware of companies, such as Abraxis Bioscience (formerly American Pharmaceutical Partners), NeoPharm and Sonus Pharmaceuticals that are applying significant resources and expertise to developing reformulations of paclitaxel for intravenous delivery. In early 2005, Abraxis Bioscience received FDA approval for and is marketing their product. None of these other reformulations has received approval from FDA. Other companies, such as Cell Therapeutics, are developing new chemical entities that involve paclitaxel conjugated, or chemically bound, to another chemical. None of these new chemical entities have received final approval from FDA. In addition, a number of companies have developed technology for delivering hydrophobic drugs. Cardinal Health, CyDex and Elan have created formulations of hydrophobic drugs that have been approved by FDA.

- **AI-128**, our initial sustained release formulation of an inhaled asthma drug, if approved for marketing and sale, will also face intense competition. Companies such as Alkermes possess technology that may be suitable for sustained release pulmonary drug delivery and may have competitive programs that have not been publicly announced or may decide to begin such programs in the future. We are not aware of any other company currently in human clinical development of a sustained release version of the asthma drug that is currently the subject of our research and development efforts. In addition, many asthma drugs are marketed by large pharmaceutical companies with much greater resources than us. These companies may be developing sustained release versions of their asthma drugs that would compete with our sustained release product candidate.

Relative to us, most of our competitors have substantially greater capital resources, research and development staffs, facilities and experience in conducting clinical trials and obtaining regulatory approvals, as well as in manufacturing and marketing pharmaceutical products. Many of our competitors may achieve product commercialization or patent protection earlier than we will. Furthermore, we believe that some of our competitors have used, and may continue to use, litigation to gain a competitive advantage. Finally, our competitors may use different technologies or approaches to the development of products similar to the products we are seeking to develop.

**We expect to develop international operations that will expose us to additional business risks.**

We expect, whether directly or through collaborative relationships, to develop operations outside the United States in order to market and distribute our products. Regardless of the extent to which we seek to develop these operations ourselves or in collaboration with others, we cannot be sure that our international efforts will be successful. Any expansion into international markets will require additional resources and management attention and will subject us to new business risks. These risks could lower the prices at which we can sell our products or otherwise have an adverse effect on our operating results. Among the risks we believe are most likely to affect any international operations are:

- different regulatory requirements for approval of our product candidates;
- dependence on local distributors;
- longer payment cycles and problems in collecting accounts receivable;
- adverse changes in trade and tax regulations;
- the absence or significant lack of legal protection for intellectual property rights;
- political and economic instability; and
- currency risks.

**Risks Related to Our Industry**

**Even if we obtain marketing approval, our products will be subject to ongoing regulatory review.**

If regulatory approval of a product is granted, such approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly, post-marketing follow-up studies. As to products for which marketing approval is obtained, the manufacturer of the product and the manufacturing facilities will be subject to continual review and periodic inspections by FDA and other regulatory authorities. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product will remain subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the product, manufacturer or facility may result in restrictions on the product or the manufacturer, including withdrawal of the product from the market. We may be slow to adapt, or we may never adapt, to changes in existing requirements or adoption of new requirements or policies.
If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

**Market acceptance of our products will be limited if users of our products are unable to obtain adequate reimbursement from third-party payors.**

Government health administration authorities, private health insurers and other organizations generally provide reimbursement for products like our product candidates, and our commercial success will depend in part on these third-party payors agreeing to reimburse providers for the costs of our products. Even if we succeed in bringing any of our proposed products to market, we cannot assure you that third-party payors, in the United States, Europe and other markets that we may pursue, will consider our products cost-effective or provide reimbursement in whole or in part for their use or agree to the proposed price.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. Each of our product candidates is intended to replace or alter existing therapies or procedures. These third-party payors may conclude that our products are less safe, effective or cost-effective than these existing therapies or procedures. Therefore, third-party payors may not approve our products for reimbursement.

If third-party payors do not approve our products for reimbursement or fail to reimburse them adequately, sales will suffer as some physicians or their patients will opt for a competing product that is approved for reimbursement or is adequately reimbursed. Even if third-party payors make reimbursement available, these payors’ reimbursement policies may adversely affect the ability of us and our potential collaborators to sell our products on a profitable basis.

Moreover, the trend toward managed healthcare in the United States, the growth of organizations such as health maintenance organizations, and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our products which could adversely affect our business, financial condition and results of operations.

In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us before or after FDA or other regulatory agencies approve any of our proposed products for marketing. While we cannot predict the likelihood of any of these legislative or regulatory proposals, if any government or regulatory agencies adopt these proposals they could materially adversely affect our business, financial condition and results of operations.

**We may be required to defend lawsuits or pay damages in connection with the alleged or actual harm caused by our products or product candidates.**

We face an inherent business risk of exposure to product liability claims in the event that the use of our products is alleged to have resulted in harm to others. This risk exists in clinical trials as well as in commercial distribution. In addition, the pharmaceutical and biotechnology industries in general have been subject to significant medical malpractice litigation. We may incur significant liability if product liability or malpractice lawsuits against us are successful. Furthermore, product liability claims, regardless of their merits, could be costly and divert our management’s attention from other business concerns, or adversely affect our reputation and the demand for our products. Although we maintain product liability insurance, we cannot be certain that this coverage will be adequate or that it will continue to be available to us on acceptable terms.

**Rapid technological change could make our products obsolete.**

Pharmaceutical technologies have undergone rapid and significant change. We expect that pharmaceutical technologies will continue to develop rapidly. Our future will depend in large part on our ability to maintain a competitive position with respect to these technologies. Any compounds, products or processes that we develop may become obsolete before we recover any expenses incurred in connection with their development. Rapid technological change could make our products obsolete, which could materially adversely affect our business, financial condition and results of operations.

**Our products involve the use of hazardous materials, and as a result we are exposed to potential liability claims and to costs associated with complying with laws regulating hazardous waste.**
Our research and development activities involve the use of hazardous materials, including chemicals and biological materials. We believe that our procedures for handling hazardous materials comply with federal and state regulations. However, there can be no assurance that accidental injury or contamination from these materials will not occur. In the event of an accident, we could be held liable for any damages, which could exceed our available financial resources. This liability could materially adversely affect our business, financial condition and results of operations.

We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products, and we spent approximately $42,000 during the nine months ended September 30, 2008 to dispose of these hazardous materials and waste products. We may be required to incur significant costs to comply with environmental laws and regulations in the future that could materially adversely affect our business, financial condition and results of operations.

Risks Related to Our Common Stock

Our common stock may be delisted from the Nasdaq Capital Market, which could negatively impact the price of our common stock and our ability to access the capital markets.

Effective at the open of business on October 29, 2008, the listing of our common stock was transferred from the Nasdaq Global Market to the Nasdaq Capital Market. This listing transfer was part of our plan of compliance as presented to the Nasdaq Hearings Panel in September 2008 in connection with our appeal of the Nasdaq Global Market delisting notice we received on July 14, 2008. We currently fail to meet The Nasdaq Stock Market LLC’s (“NASDAQ”) minimum bid price requirement of $1.00 pursuant to Marketplace Rule 4450(a)(5) and NASDAQ’s $10.0 million minimum stockholders’ equity requirement pursuant to Marketplace Rule 4450(a)(3) for continued listing on the Nasdaq Global Market. We have until December 31, 2008 to show at least $2.5 million in stockholders’ equity or demonstrate compliance with one of the alternative listing criteria for continued listing on the Nasdaq Capital Market, including $35.0 million in market value of listed securities for a minimum of ten consecutive trading days. We have until April 17, 2009 to evidence a closing bid price of $1.00 or more for a minimum of ten consecutive trading days. If we do not satisfy these requirements within these periods of time, our common stock may be delisted from NASDAQ.

In addition to the minimum bid price deficiency described above, as of September 30, 2008, we do not meet the minimum stockholders’ equity requirement for continued listing on the Nasdaq Capital Market.

The delisting of our common stock from the Nasdaq Capital Market would significantly affect the ability of investors to trade our securities and would significantly negatively affect the value and liquidity of our common stock. In addition, the delisting of our common stock could materially adversely affect our ability to raise capital on terms acceptable to us or at all. Delisting from the Nasdaq Capital Market could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities. In the event our common stock is delisted from the Nasdaq Capital Market, our common stock may become eligible for quotation and trading on the OTC Bulletin Board.

If Cephalon elects to convert its convertible promissory into shares of our common stock, it will likely result in immediate and substantial dilution to our stockholders and potentially give Cephalon control over stockholder votes.

Pursuant to the terms of the Cephalon convertible promissory note, Cephalon has the option to convert the Cephalon convertible promissory note into the number of shares of our common stock equal to 51% of our outstanding common stock on a fully-diluted basis on the date of such conversion. Such conversion will likely result in immediate and substantial dilution to our stockholders. As a majority holder of our common shares, Cephalon would be able to control certain votes of our stockholders and may also frustrate or make more difficult the acquisition of Acusphere by a third party without Cephalon’s approval. Further, under the terms of our note purchase agreement with Cephalon, during the restricted period, if we undertake an offering of certain securities, Cephalon has the right to acquire that number or amount of such shares of our securities, at the price and upon substantially the same terms and conditions as such shares are to be sold or otherwise issued to third parties, as shall enable Cephalon to maintain, on a fully diluted basis and assuming the conversion of all such securities, its ownership interest in the Company. Cephalon’s ability to maintain its ownership interest may also frustrate or make more difficult our ability to issue additional equity and/or debt securities to new investors.

If Cephalon elects to convert its convertible promissory into shares of our common stock, it will have the right to proportional representation on our board of directors, which would provide Cephalon with an opportunity to exert significant control over the strategic direction of Acusphere.
Pursuant to the terms of our note purchase agreement with Cephalon, from and after the conversion of the Cephalon convertible promissory note and for so long as Cephalon holds at least 25% or more of our outstanding voting securities, Cephalon will have the right to designate that number of directors to our board of directors that is proportional to its equity interest. Cephalon’s ability designate a proportional number of our directors would provide Cephalon with an opportunity to exert significant control over the strategic direction of the Company and may also frustrate or make more difficult the acquisition of Acusphere by a third party without Cephalon’s approval.

**We expect that our stock price will fluctuate significantly.**

The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical and biotechnology stocks. An active public market for our common stock may not continue to develop or be sustained. The volatility of pharmaceutical and biotechnology stocks and the level of trading in such stocks do not always relate to the operating performance of the companies represented by such stocks. Factors that could cause this volatility in the market price of our common stock include:

- announcements of the introduction of new products by us or our competitors;
- announcements of clinical trial results;
- market conditions in the pharmaceutical and biotechnology sectors;
- rumors relating to us or our competitors;
- litigation or public concern about the safety of our potential products;
- our quarterly operating results;
- deviations in our operating results from the estimates of securities analysts;
- sales by us of additional shares of our common or preferred stock; and
- FDA or international regulatory actions.

The market price of our common stock may also fluctuate in response to the exercise by us of rights under the terms of our 6.5% convertible exchangeable preferred stock. For example, we may elect to automatically convert the preferred stock if our common stock price has exceeded 150% of the conversion price of the preferred stock for at least 20 trading days during a 30-day trading period ending within five trading days prior to the notice of automatic conversion. There is a risk of fluctuation in the price of our common stock between the time when we may first elect to automatically convert the preferred stock and the automatic conversion date. These fluctuations may adversely affect the value of our common stock.

**If shares under our universal shelf registration statement are issued, then the price of our securities may be negatively affected.**

We have on file with the SEC a universal shelf registration statement on Form S-3 (Registration No. 333-134263), which provides for the offer, from time to time, of common stock, preferred stock, debt securities and warrants up to an aggregate remaining availability as of September 30, 2008, of approximately $33.5 million, subject to Company’s satisfaction of the criteria for use of Form S-3. The SEC declared the shelf registration statement effective on August 18, 2006. SEC rules currently limit our ability to utilize a shelf registration statement to no more than one-third of our unaffiliated public float over any twelve month period. Subject to these limitations, market conditions and our capital needs, and to the extent and so long as we are then eligible to use the registration statements under SEC rules, we may again seek to use any remaining availability under the shelf registration statements by making an offering of securities covered for sale under the registration statements. In addition, we may amend our shelf registration statements or file a new shelf registration statement to increase our potential access to capital. The addition of these securities into the market may be dilutive to existing stockholders and have an adverse effect on the price of our securities.

**Our common stock is junior to our preferred stock with respect to the right to receive payments in the event of a dissolution, liquidation or winding up of Acusphere.**

In February 2005, we issued and sold 900,000 shares of our 6.5% convertible exchangeable preferred stock. As of November 6, 2008, 310,000 of these shares of preferred stock are outstanding. The preferred stock is senior to the common stock as to liquidation. In the event of our voluntary or involuntary dissolution, liquidation or winding up of Acusphere, holders of our preferred stock will receive a liquidation preference in an amount equal to $50 per share, plus all accrued and unpaid dividends through the distribution date. Only after holders of the preferred stock have received their liquidation preference and any accrued and unpaid dividends will we distribute assets, if any are remaining, to our common stock holders.
Acusphere could be the subject of securities class action litigation due to future stock price volatility.

In the past, when the market price of a stock has been volatile, holders of that stock have often instituted securities class action litigation against the company that issued the stock. The market price of our common stock has been historically volatile and may remain volatile. Such volatility in our stock price could result in shareholder litigation against us. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

Future sales of common stock by our existing stockholders may cause our stock price to fall.

The market price of our common stock could decline as a result of sales by our existing stockholders of shares of common stock in the market, or the perception that these sales could occur. These sales might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate. As of November 6, 2008, we have approximately 49,506,766 shares of common stock outstanding and 310,000 shares of convertible preferred stock outstanding that are convertible into approximately 2.3 million shares of our common stock, plus up to a maximum of approximately 0.2 million additional shares of our common stock issuable at our option in satisfaction of the maximum dividend make-whole payment on these shares of preferred stock. All of the shares of common stock issuable upon conversion of our preferred stock will be freely tradable without restriction under the federal securities laws unless purchased by our affiliates.

The terms of our outstanding shares of preferred stock may restrict our ability to raise additional capital or hamper or prevent an acquisition of us.

In February 2005, we issued and sold 900,000 shares of our 6.5% convertible exchangeable preferred stock. As of November 6, 2008, 310,000 of these shares of preferred stock are outstanding. In the event of our voluntary or involuntary dissolution, liquidation or winding up of Acusphere, holders of our preferred stock will receive a liquidation preference in an amount equal to $50 per share, plus all accrued and unpaid dividends through the distribution date. Only after holders of the preferred stock have received their liquidation preference and any accrued and unpaid dividends will we distribute assets, if any are remaining, to our common stock holders. Without the vote or consent of the holders of at least a majority of the shares of preferred stock, we can not authorize or sell any equity security that ranks senior to the preferred stock as to dividends or distributions of assets upon liquidation, dissolution or winding up of Acusphere. As a result of this liquidation preference, it may be difficult for us to raise additional capital through the sale of common stock or junior preferred stock on acceptable terms, or at all.

In addition, without the vote or consent of the holders of at least a majority of the shares of preferred stock we may not effect a consolidation or merger with another entity unless the preferred stock that remains outstanding and its rights, privileges and preferences are unaffected or are converted into or exchanged for preferred stock of the surviving entity having rights, preferences and limitations substantially similar, but no less favorable, to the convertible preferred stock. This provision could hamper a third party’s acquisition of us or discourage a third party from attempting to acquire control of us via a merger.

Under some circumstances, the holders of our outstanding shares of preferred stock may be entitled to elect some of the directors of Acusphere.

In February 2005 we issued and sold 900,000 shares of our 6.5% convertible exchangeable preferred stock. As of November 6, 2008, 310,000 of these shares of preferred stock are outstanding. Cumulative dividends accrue on our preferred stock at an annual rate of $3.25 per share, payable quarterly on the first day of March, June, September and December, commencing June 1, 2005. Any dividends must be declared by our board of directors and must come from funds that are legally available for dividend payments. In February 2008 and May 2008, our Board of Directors elected not to declare a quarterly cash dividend that was otherwise payable on March 1, 2008 and June 1, 2008, respectively. In August 2008, our Board of Directors again elected not to declare a quarterly cash dividend in the amount of $0.8125 per share on the preferred stock that was otherwise payable on September 1, 2008. This is the third quarterly dividend that has not been declared and paid on the preferred stock. If we have not paid dividends on the preferred stock in an aggregate amount equal to at least six quarterly dividends whether or not consecutive, we must increase the size of our board of directors by two additional directors. After this time, and for so long as these dividends remain due and unpaid, holders of the preferred stock, voting separately as a class with holders of preferred stock ranking on the same basis as to dividends having like voting rights, will be entitled to elect two additional directors at any meeting of stockholders at which directors are to be elected. These directors will be appointed to classes on the board as determined by our board of directors. These voting rights will terminate.
when we have declared and either paid or set aside for payment all accrued and unpaid dividends. The terms of office of all directors so elected will terminate immediately upon the termination of these voting rights.

Provisions of Delaware law or our charter documents could delay or prevent an acquisition of us, even if the acquisition would be beneficial to our stockholders, and could make it more difficult for you to change management.

Provisions of Delaware law or our charter or by-laws could hamper a third party’s acquisition of us, or discourage a third party from attempting to acquire control of us. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock. Further, these provisions make it more difficult for stockholders to change the composition of our board of directors in any one year.

These provisions include:

- a provision allowing us to issue preferred stock with rights senior to those of the common stock without any further vote or action by the holders of the common stock;
- the existence of a staggered board of directors in which there are three classes of directors serving staggered three-year terms, thus expanding the time required to change the composition of a majority of directors and potentially discouraging someone from making an acquisition proposal for us;
- the by-laws’ requirement that stockholders provide advance notice when nominating our directors;
- the inability of stockholders to convene a stockholders’ meeting without the chairperson of the board, the chief executive officer, the president or a majority of the board of directors first calling the meeting; and
- the application of Delaware law prohibiting us from entering into a business combination with the beneficial owner of 15% or more of our outstanding voting stock for a period of three years after the 15% or greater owner first reached that level of stock ownership, unless we meet specified criteria.

In connection with our November 2008 transaction with Cephalon we waived Section 203 of the Delaware General Corporation Law and agree to seek shareholder approval of certain provisions of our certificate of incorporation, which may make it more difficult to discourage an acquisition of Acusphere by Cephalon or others.

As a condition to the consummation of our November 2008 transaction with Cephalon we waived Section 203 of the Delaware General Corporation Law, the application of which have otherwise prohibited us from entering into a business combination Cephalon without a two-thirds stockholder vote. Further, for so long as the Cephalon convertible note remains outstanding or Cephalon holds at least 25% or more of our outstanding voting securities, which period we refer to as the restricted period, Cephalon may request that we take all actions necessary to enact an amendment to our certificate of incorporation, including calling and holding a meeting of our stockholders to seek approval of such amendment and filing with the SEC a proxy statement seeking approval of such amendment, which (i) will provide that we expressly elect not to be governed by Section 203 of the Delaware General Corporation Law and/or (ii) will provide that each member of our board of directors shall be elected annually for a one year term (i.e. a “staggered board”). In the absence of these procedural protections, it would be more difficult for our board of directors to discourage an acquisition by Cephalon or others. Notwithstanding the foregoing, any future transaction between us and Cephalon must be approved by a committee of directors of our board consisting entirely of directors that are independent of Cephalon.

We have never paid dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

We have paid no cash dividends on our common stock to date and, other than cash dividends paid on our preferred stock, we currently intend to retain our future earnings, if any, to fund the development and growth of our businesses. In addition, the terms of any future debt or credit facility may preclude us from paying these dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.
ITEM 5. OTHER INFORMATION

Our policy governing transactions in our securities by its directors, officers and employees permits our officers, directors and certain other persons to enter into trading plans complying with Rule 10b5-1 under the Securities Exchange Act of 1934, as amended. We have been advised that, in accordance with Rule 10b5-1 and our policy governing transactions in our securities, such a plan has been entered into with provisions requiring that any trading of securities thereunder is to be reported when and if it occurs in accordance with applicable law. We undertake no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.

ITEM 6. EXHIBITS

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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 on this 10th day of November 2008.

ACUSPHERE, INC.

By:  /s/ Sherri C. Oberg
     Sherri C. Oberg  
     President and Chief Executive Officer

By:  /s/ Lawrence A. Gyenes
     Lawrence A. Gyenes  
     Senior Vice President and Chief Financial Officer
     (Principal Financial and Accounting Officer and Duly Authorized Officer)
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CERTIFICATIONS

I, Sherri C. Oberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Acusphere, 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 officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 13d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 13d-15(f)) for the registrant and we 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 period 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 officers 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.

Date: November 10, 2008

/s/ Sherri C. Oberg
Sherri C. Oberg
Chief Executive Officer
(Principal Executive Officer)
CERTIFICATIONS

I, Lawrence A. Gyenes, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Acusphere, 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 officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 13d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 13d-15(f)) for the registrant and we 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 period 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 officers 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.

Date: November 10, 2008

/s/ Lawrence A. Gyenes
Lawrence A. Gyenes
Chief Financial Officer
(Principal Financial Officer)
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Acusphere, Inc. (the “Company”) on Form 10-Q for the period ending September 30, 2008 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), we, Sherri C. Oberg, Chief Executive Officer of the Company, and Lawrence A. Gyenes, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to our knowledge, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Sherri C. Oberg  
Sherri C. Oberg  
Chief Executive Officer

/s/ Lawrence A. Gyenes  
Lawrence A. Gyenes  
Chief Financial Officer

November 10, 2008

This certification is being submitted solely for the purpose of complying with Section 1350 of Chapter 63 of Title 18 of the United States Code. This certification is not to be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liability of that section, nor will the certification be deemed incorporated by reference in to any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the registrant specifically incorporates it by reference.