
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): February 4, 2008

CADENCE PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33103
(Commission
File Number)

41-2142317
(IRS Employer
Identification No.)

12481 High Bluff Drive, Suite 200, San Diego, California
(Address of Principal Executive Offices)

92130
(Zip Code)

Registrant's telephone number, including area code: **(858) 436-1400**

(Former Name or Former Address, if Changed Since Last Report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01. Regulation FD Disclosure.

Theodore R. Schroeder, President and Chief Executive Officer of Cadence Pharmaceuticals, Inc. (“Cadence”), and other executive officers will be presenting the information attached as Exhibit 99.1 to this Current Report on Form 8-K commencing February 4, 2008 at various investor and analyst meetings, including at the Merrill Lynch Global Pharmaceutical, Biotechnology & Medical Device Conference in New York on February 5, 2008.

The information in this Current Report on Form 8-K, including the presentation slides attached hereto as Exhibit 99.1, is being furnished pursuant to this Item 7.01 and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

By filing this Current Report on Form 8-K and furnishing this information, Cadence makes no admission as to the materiality of any information in this Current Report on Form 8-K. The information contained in the presentation slides is summary information that is intended to be considered in the context of Cadence’s filings with the SEC and other public announcements that Cadence makes, by press release or otherwise, from time to time. Cadence undertakes no duty or obligation to publicly update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

Item 8.01. Other Events.

Cadence hereby updates its “Risk Factors” which have been provided in prior filings with the Securities and Exchange Commission. A copy of these risk factors is attached as Exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
99.1	Company Slides — dated February 4, 2008
99.2	Risk Factors

SIGNATURES

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

Date: February 4, 2008

CADENCE PHARMACEUTICALS, INC.

By: /s/ William R. LaRue

Name: William R. LaRue

Title: Senior Vice President, Chief Financial Officer,
Treasurer and Assistant Secretary

EXHIBIT INDEX

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Corporate Overview

February 2008



Improving the lives of hospitalized patients

Ted Schroeder

President, CEO & co-founder

Forward-looking statements

This presentation contains forward-looking statements, including statements regarding: the timeframes in which we expect to complete and disclose results from our clinical trials; the timeframes in which we expect to file submissions to regulatory authorities seeking marketing authorization for our product candidates, and the potential scope of those submissions; the ability of our product candidates to address unmet medical needs and be commercially successful; and the anticipated revenue and market potential of our product candidates.

The inclusion of forward-looking statements should not be regarded as a representation by Cadence that any of its plans will be achieved. Actual results may differ materially from those included in this presentation due to the risks and uncertainties inherent in our business, including, without limitation: our dependence on the success of our only two product candidates; delays in completing clinical trials or achieving our product development goals, or significant issues regarding the design or execution of our clinical trials; the results of our clinical trials, and whether the FDA agrees with our analyses of these results; whether the results of our clinical trials are unfavorable or inconsistent with previous trial results; the potential need to expand our ongoing clinical trials or to conduct additional clinical trials; the market potential for our product candidates, and our ability to compete with new or existing products; unanticipated adverse side effects or inadequate therapeutic efficacy of our product candidates; delays or quality issues with respect to completion of pre-commercialization manufacturing development activities; the scope, validity and limitations in our patent rights, and our ability to maintain patent protection for our product candidates; the need to obtain substantial additional funding to complete our clinical development programs and successfully launch our products; other difficulties or delays in developing, testing, manufacturing, obtaining regulatory approval for, and marketing our product candidates; and other risks detailed in Cadence's press releases and public filings with the U.S. Securities and Exchange Commission.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and Cadence undertakes no obligation to revise or update this presentation to reflect events or circumstances that occur after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

Cadence: highlights

- **Hospital-focused business strategy**

Acquire, develop and commercialize late stage products

Target \$50+ billion US hospital market with focused sales force



- **Acetavance™ – Phase III for acute pain and fever (US)**

Market leading injectable analgesic in EU – BMS '07 sales ~80 million units

Opioid sparing potential

505(b)2 path to US FDA approval



- **Omigard™ – Phase III for catheter-related infections (US/EU)**

Large unmet need – impact on patient care and costs to hospitals

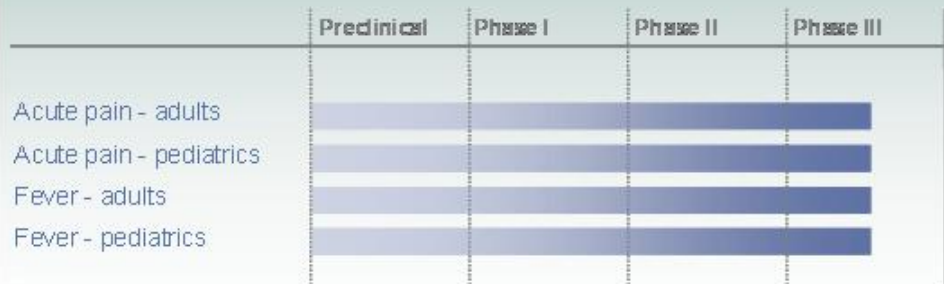
Primary endpoint in ongoing Phase III trial achieved as secondary in previous trial

SPA path to US FDA approval



Acetavance™

intravenous acetaminophen



Acetavance™: product overview



- **Oral acetaminophen - most widely used drug for pain and fever**

Available in US for 50+ years

Active ingredient in Tylenol® and 300+ medications

- **Acetavance – proprietary IV formulation**

Marketed by BMS in Europe since 2002 (Perfalgan™)

Cadence acquired US and Canadian rights from BMS

Acetavance™: limitations of current IV therapies

Opioids

- Sedation
- Nausea
- Vomiting
- Constipation
- Headache
- Cognitive impairment
- Respiratory depression



- **Prolonged recovery**
- **Increased length of stay**
- **Higher costs to the institution**

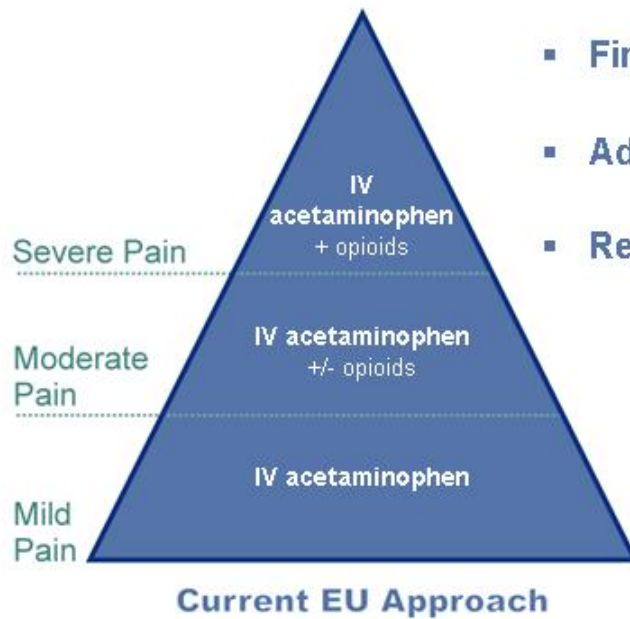
NSAIDs

- Black Box Warning
- Bleeding
- GI complications
- Kidney complications
- Cardiovascular risks



- **Limited use**

Acetavance™: foundation of multi-modal analgesia



- **First analgesic drug post-op**
- **Add opioids if pain increases**
- **Result¹:**
 - >33% decrease in opioids
 - Superior pain relief
 - Better patient satisfaction

¹Sinatra, et al. *Anesthesiology*. April 2005

Acetavance™: EU market leader



European IV Acetaminophen Sales



- EU market share leader: 21% share of all injectable analgesics (1H07)
- \$2.50 average price/unit – \$7-9 in select European countries

Acetavance™: large US market opportunity

Market Size

- **278 million IV analgesic units¹ (2006)**
Acetavance expected to grow market

Share

- **EU: 21% of all IV analgesic units**
Upside potential

Pricing

- **\$7/vial Toradol® US price in 1997**
Upper limit of pricing to be tested

Sales

- **Significant product opportunity**

¹Source: IMS

Acetavance™: abdominal GYN surgery (301) results

- **Treatment of pain following abdominal gynecologic surgery**

Acetavance vs. placebo over 48 hours

- **Primary endpoint (SPI-24/48hrs) not statistically significant**

Huge standard deviation in pain scores immediately post-op

- **Positive secondary endpoints:**

Pain relief

Patient global satisfaction

Time to rescue medication

- **Excellent safety results**

Adverse events and LFTs not different from placebo

Acetavance™: demonstrated safety and efficacy

Safety

- ~2,000 subjects received IV acetaminophen in clinical trials
- ✓ Safety consistent with oral acetaminophen
- 48 hour safety first established in Cadence 301 study
- ✓ Adverse events equal or slightly below placebo

Efficacy

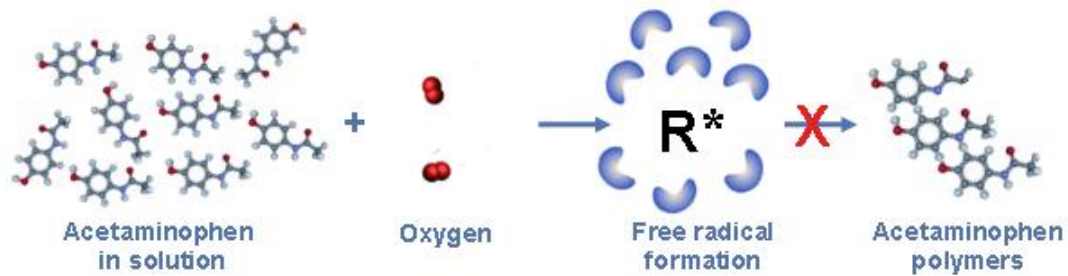
- 10 successful, randomized, placebo-controlled, post-operative pain trials completed with IV acetaminophen

Acetavance™: 505(b)2 path to NDA

<u>Requirement</u>	<u>Study</u>	<u>Status</u>
<input checked="" type="checkbox"/> Single dose PK	BMS-9805IC-CIS (Dietlin)	Complete
<input checked="" type="checkbox"/> Multiple dose PK – adults	CADX 101	Complete
<input checked="" type="checkbox"/> Single dose efficacy – fever	CADX 302	Complete
<input checked="" type="checkbox"/> 24 hr efficacy – orthopedic	BMS-RC-201-3002 (Sinatra)	Complete
<input checked="" type="checkbox"/> 48 hr safety	CADX 301	Complete
<input type="checkbox"/> Multiple dose PK – peds	CADX 102	Ongoing
<input type="checkbox"/> 24 hr efficacy – soft tissue	CADX 304	Ongoing
<input type="checkbox"/> 5 day safety – adults	CADX 351	1Q08 initiation
<input type="checkbox"/> 5 day safety peds	CADX 352	1Q08 initiation
<input type="checkbox"/> 48 hr efficacy	<i>Requirement TBD with FDA</i>	

IV Acetaminophen: strong intellectual property

Formulation must protect acetaminophen from O₂ degradation



Issued US process & product-by-process patent

- Covers process for removing oxygen from a solution and solutions made by that process
- Expires in 2021

Issued US formulation patent

- Covers all acceptable formulations containing radical scavengers and/or radical antagonists
- Expires in 2017



Omigard™

omiganan 1% aqueous gel



Omigard™: product overview

Cadence acquired North American and European rights



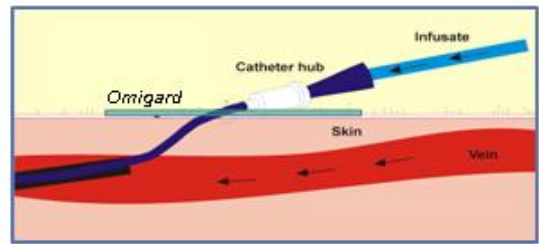
- **Topical antimicrobial for catheter-related infections**
 - Bactericidal *and* fungicidal
 - Rapid *and* prolonged effect
- **Powerful resistance profile**
- **Excellent safety profile**
- **Convenient application**
- **Composition of matter to 2017 plus extensions**

Omigard™: significant unmet need

- **Catheters are leading cause of BSI**

 - 325,000 catheter-related BSIs

 - 40,000 - 80,000 deaths



- **Mounting pressures to lower infection rates**

 - Mandatory hospital reporting

 - Changes in CMS reimbursement

 - \$25,000 per infection

- **Significant limitations with current standard of care**

 - Limited duration of activity

 - Increasing resistance

Omigard™: large market opportunity

- **20 million central lines placed in US**
 - 11 million CVCs
 - 7 million arterial lines
 - 2 million PICCs
- **9% CAGR**
- **3 to 4 applications of Omigard per catheter**
 - Dressing change and reapplication every 3 days
- **>50 million potential applications of Omigard in US**



Omigard™: clear path to FDA approval

- **Special Protocol Assessment (SPA) completed with FDA**

Single confirmatory Phase III trial required for approval

Primary endpoint: Local Catheter Site Infection (LCSI)

42% LCSI reduction ($p=0.03$) demonstrated in previous Phase III study (n=1,407)

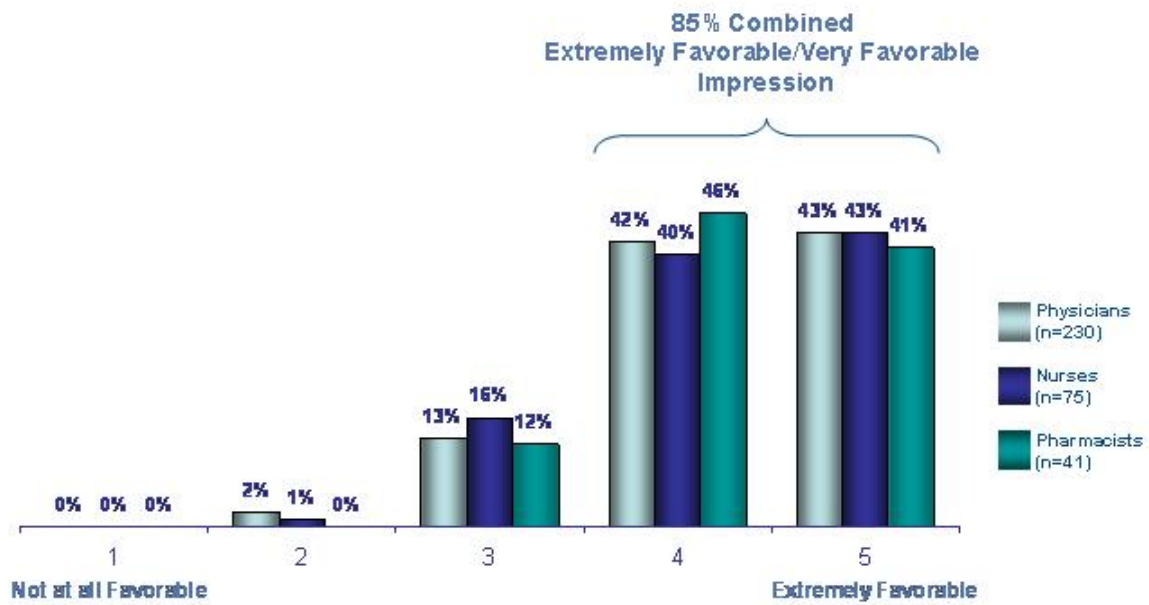
- **Phase III CLIRS trial: Central Line Infection Reduction Study**

1,850 patients in the US and Europe

Enrollment completion expected 2Q08

- **Fast Track Status**

Omigard™: perceived as major advancement



Harris Interactive, Inc. November 2006

Cadence: key milestones

- ❑ **Acetavance “speed of onset” fever trial results** 1Q08
- ❑ **Acetavance FDA meeting** 2Q08
- ❑ **Acetavance Phase III laparoscopic surgery results** 2H08
- ❑ **Omigard Phase III CLIRS results** 2H08
- ❑ **Acetavance NDA submission** 1H09*
- ❑ **Omigard NDA submission** 1H09

* Subject to discussions with FDA

Cadence: experienced management team

Individual/Title	Select Previous Affiliations
Ted Schroeder President, CEO & co-founder	BMS, Dura, Elan
Jim Breitmeyer, MD, PhD EVP, Development & Chief Medical Officer	Serono, AME, Lilly
Hazel Aker, JD SVP, General Counsel	Alaris, CancerVax, Ambrx
Bill Craig, PhD SVP, Pharmaceutical Development & Manufacturing	Telios, Alpha, ISTA
Bill LaRue SVP, Chief Financial Officer	SafeSkin, CancerVax
Cathy Hardalo, MD VP, Clinical Development	Schering Plough
Malvina Laudicina VP, Regulatory Affairs and Quality Assurance	Schering-Plough, Dura, Pfizer
Mike Royal, MD, JD VP, Clinical Development, Analgesics	Elan, Alpharma, Solstice
David Socks VP, Business Development & co-founder	Windamere Venture Partners

Cadence: financial position

Nine months ended September 30, 2007:

Operating expenses \$39.6 million

Shares outstanding 29.1 million

As of December 31, 2007:

Cash and cash equivalents \$56 million



Cadence: highlights

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NASDAQ: CADX



Improving the lives of hospitalized patients

Risk Factors

Below are updated risk factors relating to us and our business. These factors represent risks and uncertainties that could cause actual results to differ materially from those implied by forward-looking statements contained in this report, including the presentation slides furnished as Exhibit 99.1, and other written reports and oral statements made from time to time by us. We caution you that statements included in the presentation slides that are not a description of historical facts are forward-looking statements. These statements are based on our current beliefs and expectations. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and we undertake no obligation to revise or update this report to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

These risk factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, which has been updated since the filing of our Annual Report on Form 10-K for the year ended December 31, 2006, in its entirety, as well as our other public filings with the Securities and Exchange Commission.

In the near-term, the success of our business will depend on many factors, including the following risks:

- we are largely dependent on the success of our only two product candidates, Acetavance and Omigard, and we cannot be certain that our ongoing and planned clinical development programs will be successful, or sufficient to support new drug applications, or NDAs, or that either product candidate will receive regulatory approval or be successfully commercialized;
 - delays in the commencement, enrollment or completion of clinical testing for either of our product candidates, or significant issues regarding the adequacy of our clinical trial designs or the execution or success of our clinical trials, could result in increased costs to us and delay or limit our ability to obtain regulatory approval;
 - the outcome of final analyses of data from our clinical trials of Acetavance or Omigard may vary from our initial analyses, and the U.S. Food and Drug Administration, or FDA, may not agree with our interpretation of these results;
 - ongoing or planned clinical trials of Acetavance or Omigard may produce negative or inconclusive results, or may be inconsistent with previous clinical trial results, and we may decide, or the FDA may require us, to conduct additional clinical trials or to modify our ongoing clinical trials;
 - even if our product candidates are approved by regulatory authorities, the market potential for pain, fever, local catheter site infections and other target markets may be less than anticipated, and we expect intense competition in the hospital marketplace for our targeted indications;
 - unexpected adverse side effects or inadequate therapeutic efficacy of Acetavance or Omigard could delay or prevent regulatory approval or commercialization of our product candidates, or result in recalls or product liability claims against us;
 - delays or quality issues with respect to the completion of required pre-commercialization manufacturing development activities for our product candidates, including the completion of adequate stability data, could result in increased costs to us and delay or limit our clinical trials and our ability to obtain regulatory approval;
 - the patent rights that we have in-licensed covering Acetavance are limited to a specific intravenous formulation of acetaminophen, and our market opportunity for this product candidate may be limited by the lack of patent protection for the active ingredient itself and other formulations that may be developed by competitors;
-

- we will require substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our development programs and commercialization efforts; and
- we may not be able to maintain patent protection for our products and to commercialize our products without infringing the patent rights of others.

Each of these factors, as well as other factors that may impact our business, are described in more detail in the following discussion. Although the factors highlighted above are among the most significant, any of the following factors could materially adversely affect our business or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time, and you should consider all of the factors described when evaluating our business.

Risks Related to Our Business and Industry

We are largely dependent on the success of our two product candidates, Acetavance and Omigard, and we cannot be certain that either of these product candidates will receive regulatory approval or be successfully commercialized.

We currently have no drug products for sale and we cannot guarantee that we will ever have marketable drug products. The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA, and other regulatory authorities in the U.S. and other countries, which regulations differ from country to country. We are not permitted to market our product candidates in the U.S. until we receive approval of a New Drug Application, or NDA, from the FDA. We have not submitted an NDA or received marketing approval for either of our product candidates. Obtaining approval of an NDA is a lengthy, expensive and uncertain process. We currently have only two product candidates and our business success currently depends entirely on their successful development and commercialization.

We have not developed either of our product candidates independently. In March 2006, we in-licensed rights to intravenous acetaminophen from Bristol-Myers Squibb Company, or BMS, which currently markets this product in Europe for the treatment of acute pain and fever. Our clinical development program for this product candidate currently comprises eight clinical trials, including three pivotal, Phase III efficacy trials, two pharmacokinetic studies and two safety studies. In January 2008, we announced that our Phase III efficacy trial of Acetavance for the treatment of pain in adults following abdominal gynecological surgery did not meet its primary endpoint of demonstrating a statistically significant reduction in patients' pain intensity scores over 48 hours compared to placebo. As a result, we have requested a meeting with the FDA to obtain the agency's advice regarding our development program for this product candidate. Following our discussions with the FDA, we may decide or the FDA may require us to conduct additional clinical trials of Acetavance, or to modify our ongoing clinical trials of this product candidate, which would increase our costs and delay or limit our ability to obtain regulatory approval. Depending upon the results of these discussions with the FDA and assuming successful completion of all of our planned clinical trials for this product candidate, we currently plan to submit a 505(b)(2) NDA to the FDA in the first half of 2009 requesting marketing approval of Acetavance for the treatment of acute pain and fever in adults and children. Additional clinical trials may be required to support the approval of these indications and any additional indications or dosages for Acetavance, which could delay, or limit the scope of, any regulatory approvals for this product candidate. Our failure to achieve our product development goals for Acetavance in a timely manner or at all could adversely affect our business and our stock price.

In July 2004, we in-licensed the rights to our only other product candidate, omigagan pentahydrochloride 1% aqueous gel, or Omigard™, which is currently being evaluated in a single Phase III clinical trial for the prevention of local catheter site infections, or LCSIs, and will require the successful completion of this Phase III clinical trial before we are able to submit an NDA to the FDA for approval. In July 2007, we announced that the FDA agreed with our proposal to increase the number of patients to be enrolled in our ongoing Phase III clinical trial of Omigard from 1,250 to 1,850 patients. Increasing the number of patients will require greater financial resources than originally anticipated and delay the completion of enrollment in this trial from the second half of 2007 to the second quarter of 2008.

These clinical development programs for Acetavance and Omigard may not lead to commercial products if our clinical trials fail to demonstrate that our product candidates are safe and effective and, as a result, we fail to obtain necessary approvals from the FDA and similar foreign regulatory agencies. We may also fail to obtain the necessary approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process. Any failure to obtain approval of Acetavance or Omigard would have a material and adverse impact on our business.

If clinical trials of our current or future product candidates do not produce results necessary to support regulatory approval in the U.S. or elsewhere, we will be unable to commercialize these products.

To receive regulatory approval for the commercial sale of Acetavance, Omigard or any other product candidates that we may in-license or acquire, we must conduct, at our own expense, adequate and well-controlled clinical trials to demonstrate efficacy and safety in humans. Clinical testing is expensive, takes many years and has an uncertain outcome. Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing.

For example, Migenix Inc., or Migenix, the licensor for our Omigard product candidate, together with its former collaborator, Fujisawa Healthcare, Inc., or Fujisawa, completed enrollment in a Phase III clinical trial in February 2003 that demonstrated statistically significant results for the secondary endpoints of the trial: the prevention of LCSIs and catheter colonization, which is the growth of microorganisms on the portion of the catheter below the skin surface. However, the trial did not show statistical significance for the primary endpoint, the prevention of catheter-related bloodstream infections, or CRBSIs. After the termination of the collaboration between Migenix and Fujisawa in January 2004, we in-licensed the rights to Omigard from Migenix in July 2004 and subsequently reached an agreement under the SPA process with the FDA concerning the protocol for our own Phase III clinical trial of Omigard. In connection with the SPA for Omigard, the FDA agreed that a single confirmatory Phase III trial will be required for approval for Omigard and that the prevention of LCSIs will be the sole primary efficacy endpoint, and we initiated this clinical trial in August 2005. In July 2007, we announced that the FDA agreed with our proposal to increase the number of patients to be enrolled in our ongoing Phase III clinical trial of Omigard from 1,250 to 1,850 patients. This proposal was prompted by our planned re-analysis of data from the initial Phase III clinical trial of Omigard. Using a slightly different, stricter definition of LCSIs, the re-analysis indicated a statistically significant reduction in the number of LCSIs of 42% in the Omigard treatment arm as compared to the povidone-iodine treatment arm, while the original analysis of data from this trial indicated a statistically significant reduction of LCSIs of approximately 49%. Because the target sample size for our ongoing Phase III clinical trial of Omigard is based, in part, upon the LCSI rate and treatment effect of the original Phase III clinical trial of this product candidate, we determined that adding patients would be prudent in order to maintain the statistical power of the study. Additionally, improvements to hospital infection prevention practices since our Phase III clinical trial of Omigard began may reduce catheter-related infection rates, which we believe further supports the planned increase in the number of patients. Increasing the number of patients enrolled in the Omigard Phase III clinical trial will require greater financial resources than originally anticipated and delay the completion of enrollment from the second half of 2007 to the second quarter of 2008. However, we cannot be certain that our ongoing Phase III clinical trial of Omigard will be able to enroll an adequate number of patients in the trial or ultimately demonstrate statistical significance or otherwise demonstrate sufficient efficacy and safety to support the filing of an NDA or ultimately lead to regulatory approval. Furthermore, despite having completed the SPA process, the FDA's agreement with us on the trial protocol remains subject to future advances in the field or future public health concerns unrecognized at the time of the FDA's protocol assessment, and any further changes we may propose to the protocol will remain subject to the FDA's approval.

Our clinical development programs are subject to the risk of failure inherent in the development of new drugs, and our clinical trials may not demonstrate the safety, tolerability and effectiveness of our product candidates. For example, in January 2008, we announced that our Phase III efficacy trial of Acetavance for the treatment of pain in adults following abdominal gynecological surgery did not meet its primary endpoint of demonstrating a statistically significant reduction in patients' pain intensity scores over 48 hours compared to placebo. Delays in completing our clinical trials or the rejection of data from a clinical trial by regulatory authorities will result in increased development costs and could have a material adverse effect on the development of our product candidates. In

addition, our failure to adequately demonstrate the efficacy and safety of Acetavance, Omigard or any other product candidates that we may in-license or acquire would prevent receipt of regulatory approval and, ultimately, the commercialization of that product candidate.

Because the results of earlier clinical trials are not necessarily predictive of future results, Acetavance, Omigard or any other product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Success in clinical testing and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of the investigational drug. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in Phase III clinical trials, even after promising results in earlier clinical trials.

In March 2006, we in-licensed the rights to Acetavance from BMS, which is currently marketing intravenous acetaminophen in Europe and other parts of the world under the brand name Perfalgan. BMS has completed nine clinical trials, mostly in Europe, primarily in support of European regulatory approvals for this product candidate. However, we do not know at this time what regulatory weight, if any, the U.S. and Canadian regulatory agencies will give to these clinical data in supplementing clinical data generated by us for potential regulatory approval of Acetavance in the U.S. and Canada. The FDA and foreign regulatory agencies may reject these clinical trial results if they determine that the clinical trials were not conducted in accordance with requisite regulatory standards and procedures. Furthermore, we have not audited or verified the accuracy of the primary clinical data provided by BMS and cannot determine their applicability to our regulatory filings. Even though BMS has obtained marketing approval in Europe and other territories for Acetavance, we must conduct additional adequate and well controlled clinical trials in the U.S. to demonstrate Acetavance's safety and efficacy in specific indications to gain regulatory approval in the U.S.

In January 2008, we announced top-line results for our Phase III efficacy trial of Acetavance for the treatment of pain in adults following abdominal gynecological surgery. This trial did not meet its primary endpoint of demonstrating a statistically significant reduction in patients' pain intensity scores over 48 hours compared to placebo. However, this same trial did meet several secondary endpoints, including pain relief, global patient satisfaction and time to rescue medication. We also announced the results of a Phase III clinical trial of Acetavance for the treatment of fever in adults, which successfully met its primary endpoint, demonstrating a statistically significant reduction of endotoxin-induced fever over six hours compared to placebo, and key secondary endpoints. As a result of the outcome of these recently-completed clinical trials of Acetavance, we have requested a meeting with the FDA to obtain the agency's advice regarding our development program for this product candidate. Following our discussions with the FDA, we may decide or the FDA may require us to conduct additional clinical trials, or to modify our ongoing clinical trials of this product candidate, which would increase our costs and delay or limit our ability to obtain regulatory approval. The outcome of final analyses of data from our recently-completed clinical trials of Acetavance, or from other studies that we may conduct, may vary from our initial analyses, and the FDA may not agree with our interpretation of these results. Additional clinical trials may be required to support the approval of these indications and any additional indications or dosages for Acetavance, which could delay, or limit the scope of, any regulatory approvals for this product candidate, and we may not be able to demonstrate the same safety and efficacy for Acetavance in our planned and ongoing Phase III clinical trials as was demonstrated previously by BMS. Further, if subsequent trial results are unfavorable or insufficient, we may be forced to further revise the development plan for this product candidate, which could involve additional significant expense and delay.

Our other product candidate, Omigard, is a novel antimicrobial peptide and is not yet approved in any jurisdiction. No antimicrobial peptide has been approved by the FDA, including two antimicrobial peptides with mechanisms of action similar to Omigard that were studied in Phase III clinical trials. Although Omigard has been studied in more than 750 patients, all of the patients studied were enrolled in trials conducted or sponsored by Migenix or Fujisawa. Similar to Acetavance, we obtained electronic databases from the completed Phase III clinical trials sponsored by Migenix and Fujisawa. As a part of our standard procedure for analyzing data to prepare a final report of the study for a potential New Drug Application or other applications for marketing authorization, we re-analyzed the data using a slightly different, stricter definition of LCSIs. In April 2007, we announced that our re-analysis indicated a statistically significant reduction in the number of LCSIs of 42% in the Omigard treatment arm

as compared to the povidone-iodine treatment arm, while the original analysis indicated a statistically significant reduction of LCSIs of approximately 49%. Because the target sample size for our own Phase III clinical trial of Omigard is based, in part, upon the LCSI rate and treatment effect of the original Phase III clinical trial of this product candidate, we determined that adding patients would be prudent in order to maintain the statistical power of the study. In July 2007, we announced that the FDA agreed with our proposal to increase the number of patients to be enrolled in our ongoing Phase III clinical trial of Omigard from 1,250 to 1,850 patients. Increasing the number of patients enrolled in the Phase III clinical trial of Omigard will require greater financial resources than originally anticipated and delay the completion of enrollment from the second half of 2007 to the second quarter of 2008. Our audit and verification of the accuracy of the primary clinical data provided by our licensor and its former collaborator are continuing, and we cannot determine their applicability to our regulatory filings. Although the Phase III clinical trial of Omigard conducted by Migenix and Fujisawa demonstrated favorable, statistically significant results for the prevention of LCSIs and catheter colonization, secondary endpoints in their trial, we may not observe similar results in our ongoing Phase III clinical trial. Furthermore, the earlier Phase III clinical trial failed to show statistical significance for the primary endpoint of that trial, the prevention of CRBSIs. While we will measure the prevention of CRBSIs as a secondary endpoint in our ongoing Phase III clinical trial of Omigard, our trial is not designed to demonstrate statistical significance for this secondary endpoint. Although we are targeting a different primary endpoint in our trial, the prevention of LCSIs, it is possible that we will experience similar, unexpected results. Failure to satisfy a primary endpoint in a Phase III clinical trial would generally mean that a product candidate would not receive regulatory approval without one or more further successful Phase III clinical trials.

The data collected from our clinical trials may not be adequate to support regulatory approval of Acetavance, Omigard or any other product candidates that we may in-license or acquire. Moreover, all clinical data reported is taken from databases that may not have been fully reconciled against medical records kept at the clinical sites. As a result of auditing the data from these earlier clinical trials and completing the extensive re-analyses that we will need to perform as part of our standard procedures for preparing final reports of these studies, the previously reported results may change, which may negatively impact our ongoing Phase III clinical trials, or the suitability of earlier clinical trials for inclusion in applications for marketing authorization of our Acetavance and Omigard product candidates. As a result, despite the results reported by others in earlier clinical trials for our product candidates, we do not know whether any Phase III or other clinical trials that we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates.

Delays in the commencement or completion of clinical trials, or significant issues regarding the adequacy of our clinical trial designs or the success or execution of our clinical trials, could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.

If we experience delays in the commencement or completion of our clinical trials, we could incur significantly higher product development costs and our ability to obtain regulatory approvals for our product candidates could be delayed. We may also fail to obtain the necessary regulatory approvals if we have inadequate financial or other resources to advance our product candidates through the clinical trial process. We do not know whether enrollment in our planned and ongoing clinical trials of Acetavance will be completed on time, whether our additional planned and ongoing clinical trials for Acetavance will be completed on schedule, if at all, or whether we will decide, or the FDA may require us, to increase the number of patients enrolled in our ongoing clinical trials. Additional clinical trials may be required to support regulatory approvals for the treatment of acute pain and fever in adults and children and for any additional indications or dosages for Acetavance, which could delay or limit the scope of any regulatory approvals we may receive for this product candidate. In July 2007, we announced an estimated delay in the completion of enrollment for our ongoing Phase III clinical trial of Omigard from the second half of 2007 to the second quarter of 2008, because of our decision to increase the number of patients to be enrolled in this trial, and we do not know if this clinical trial will be completed on schedule, or at all. In January 2008, we announced that our Phase III efficacy trial of Acetavance for the treatment of pain in adults following abdominal gynecological surgery did not meet its primary endpoint of demonstrating a statistically significant reduction in patients' pain intensity scores over 48 hours compared to placebo. Following our discussions with the FDA regarding the results of this trial, we may decide or the FDA may require us to conduct additional clinical trials of Acetavance, or to modify our ongoing clinical trials of this product candidate, which would increase our costs and delay or limit our ability to obtain regulatory approval. As a result, we currently anticipate that our submission of a 505(b)(2) NDA to the FDA for Acetavance may be delayed from the second half of 2008 to the first half of 2009. Depending upon the results of our discussions with the FDA and the results of our other clinical trials for this product candidate, we may further delay this estimated submission date.

The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates or may not be eligible to participate in or may be required to withdraw from a clinical trial as a result of changing standards of care. For example, we believe that improvements to hospital infection prevention practices since we commenced enrollment in our Phase III clinical trial of Omigard may reduce catheter-related infection rates, which may result in the occurrence of an insufficient number of infections to demonstrate statistical significance in this clinical trial or require an even larger number of patients to be enrolled in order to demonstrate a statistically significant effect. Although the FDA agreed with our proposal to increase the number of patients to be enrolled in our ongoing Phase III clinical trial of Omigard, we may be unable to enroll an adequate number of patients and, even if we enroll our target number of additional patients, we may still be unable to demonstrate statistical significance or otherwise demonstrate sufficient efficacy and safety to support the filing of an NDA for Omigard. The commencement and completion of clinical trials can be delayed for a variety of other reasons, including delays related to:

- reaching agreements on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining regulatory approval to commence or amend a clinical trial;
- obtaining institutional review board approval to commence or amend a clinical trial at a prospective site;
- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for the same indication as our product candidates; and
- retaining patients who have initiated a clinical trial but who may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues, side effects from the therapy or who are lost to further follow-up.

In addition, a clinical trial may be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspections of our own clinical trial operations, the operations of our CROs, or our clinical trial sites by the FDA or other regulatory authorities, which may result in the imposition of a clinical hold or, potentially, prevent us from using some of the data generated from our clinical trials to support requests for regulatory approval of our product candidates;
- new information suggesting unacceptable risk to subjects, or unforeseen safety issues or any determination that a trial presents unacceptable health risks;
- new information suggesting that the target condition occurs too infrequently for the product candidate to demonstrate efficacy; or
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties.

Additionally, changes in regulatory requirements and guidance may occur, or new information concerning the product candidate or the target medical condition may emerge, and we may need to perform additional, unanticipated non-clinical testing of our product candidates or amend clinical trial protocols to reflect these developments. Additional non-clinical testing would add costs and could delay or result in the denial of regulatory approval for a product candidate. Amendments may require us to resubmit our clinical trial protocols to institutional

review boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same indications may have been introduced to the market and established a competitive advantage.

We expect intense competition in the territories in which we have rights to our product candidates, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. There can be no assurance that developments by others will not render our product candidates obsolete or noncompetitive. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render our product candidates obsolete or noncompetitive.

We intend to develop Acetavance for the treatment of acute pain in the hospital setting, which will compete with well-established products for this and similar indications, including opioids such as morphine, fentanyl, meperidine and hydromorphone, each of which is available generically from several manufacturers, and several of which are available as proprietary products using novel delivery systems, as well as an extended release injectable (epidural) formulation of morphine, DepoDur. Ketorolac, an injectable non-steroidal anti-inflammatory drug, or NSAID, is also available generically in the U.S. from several manufacturers and used to treat acute pain. During the time that it will take us to obtain regulatory approval for Acetavance, if at all, we anticipate that several additional products may be developed for the treatment of acute pain, including other injectable NSAIDs, novel opioids, new formulations of currently available opioids, long-acting local anesthetics and new chemical entities as well as alternative delivery forms of various opioids and NSAIDs.

We are also developing our Omigard product candidate for the prevention of catheter-related infections in the hospital setting. If approved, Omigard will compete with well-established topical products that are currently used in practice to prevent these infections as well as BioPatch, a device marketed by Johnson & Johnson, which has been approved for wound dressing and prevention of catheter-related infections. Other competitive products may also be under development.

In addition, competitors may seek to develop alternative formulations of our product candidates that address our targeted indications that do not directly infringe on our in-licensed patent rights. For example, we are aware of several U.S. and Canadian patents and patent applications covering various potential injectable formulations of acetaminophen, including intravenous formulations, as well as methods of making and using these potential formulations. Furthermore, there are third-party patents covering analogs of omiganan and Migenix has patented analogs of omiganan that are not licensed to us. The commercial opportunity for our product candidates could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our in-licensed patents. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
 - development resources, including personnel and technology;
 - clinical trial experience;
 - regulatory experience;
 - expertise in prosecution of intellectual property rights; and
 - manufacturing, distribution and sales and marketing experience.
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As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, useful and less costly than ours and may also be more successful than us in manufacturing and marketing their products. We also expect to face similar competition in our efforts to identify appropriate collaborators or partners to help develop or commercialize our product candidates in markets outside the U.S.

If any of our product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

The commercial success of our product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by the medical community and coverage and reimbursement of them by third-party payors, including government payors. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

- limitations or warnings contained in a product's FDA-approved labeling, including potential limitations or warnings for Acetavance that may be more restrictive than oral formulations of acetaminophen;
- changes in the standard of care for the targeted indications for either of our product candidates could reduce the marketing impact of any superiority claims that we could make following FDA approval;
- limitations inherent in the approved indication for either of our product candidates compared to more commonly-understood or addressed conditions, including, in the case for Omigard, the ability to promote Omigard to hospitals and physicians who may be more focused on an indication specifically for the prevention of CRBSIs compared to the prevention of LCSIs, the primary endpoint in our ongoing Phase III clinical trial; and
- potential advantages over, and availability of, alternative treatments, including, in the case of Acetavance, a number of products already used to treat acute pain in the hospital setting, and in the case for Omigard, a number of competitive topical products as well as a device that has been approved for wound dressing and prevention of catheter-related infections.

Our ability to effectively promote and sell our product candidates in the hospital marketplace will also depend on pricing and cost effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. Since many hospitals are members of group purchasing organizations, which leverage the purchasing power of a group of entities to obtain discounts based on the collective buying power of the group, our ability to attract customers in the hospital marketplace will also depend on our ability to effectively promote our product candidates to group purchasing organizations. We will also need to demonstrate acceptable evidence of safety and efficacy as well as relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

The decreasing use of the comparator product in our clinical trial of Omigard and improvements in hospital infection control practices that lower catheter infection rates may limit our ability to complete the trial in a timely manner and hinder the competitive profile of this product candidate.

Over the last several years, many hospitals, particularly in the U.S., have increased the use of a particular antiseptic, chlorhexidine, as their standard of care to sterilize catheter insertion sites. Although we believe 10% povidone-iodine continues to be used by a sufficient number of hospitals to support continued enrollment of patients in our Phase III clinical trial of Omigard, this changing standard of care limits the number of potential clinical trial sites available to us. Accordingly, it may be difficult for us to maintain the clinical trial sites that we have already

retained for the Omigard trial if any of these institutions elects to replace our comparator product with chlorhexidine, and it may take us longer than anticipated to identify and reach terms with additional hospitals to serve as clinical trial sites for the trial. Delays in the completion of enrollment or clinical testing for our ongoing Phase III clinical trial of Omigard and any other studies we may conduct to compare Omigard to chlorhexidine or another topical antiseptic could significantly affect our product development costs, our prospects for regulatory approval and our ability to compete. Furthermore, the decreasing use of 10% povidone-iodine in favor of chlorhexidine could reduce the marketing impact of any superiority claims that we could make following FDA approval. For example, hospitals and physicians may be reluctant to adopt the use for Omigard in combination with chlorhexidine antiseptics for the prevention of LCSIs. Additionally, we believe that improvements to hospital infection control practices since we commenced enrollment in our ongoing Phase III clinical trial of Omigard may reduce catheter-related infection rates, which may result in the occurrence of an insufficient number of infections to demonstrate statistical significance in this clinical trial or require an even larger number of patients to be enrolled in order to demonstrate a statistically significant effect. Even if Omigard is approved by the FDA, if this product candidate does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may be unable to generate sufficient revenues to recover our development costs or otherwise sustain and grow our business.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Any of these restrictions or requirements could adversely affect our potential product revenues. For example, the label ultimately approved for Acetavance, Omigard or any other product candidates that we may in-license or acquire, if any, may include a restriction on the term of its use, or it may not include one or more of our intended indications.

Our product candidates will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, such as current Good Manufacturing Practices, or cGMPs, a regulatory agency may:

- issue warning letters or untitled letters;
 - require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
 - impose other civil or criminal penalties;
 - suspend regulatory approval;
 - suspend any ongoing clinical trials;
 - refuse to approve pending applications or supplements to approved applications filed by us;
 - impose restrictions on operations, including costly new manufacturing requirements; or
 - seize or detain products or require a product recall.
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Even if our product candidates receive regulatory approval in the U.S., we may never receive approval or commercialize our products outside of the U.S.

Our rights to Acetavance are limited to the U.S. and Canada, and our rights to Omigard are limited to North America and Europe. In order to market any products outside of the U.S., we must comply with numerous and varying regulatory requirements of other countries regarding non-clinical testing, manufacturing, safety and efficacy. 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 detailed above regarding FDA approval in the U.S. as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the U.S. As described above, such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales and potential royalties, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

We have never marketed a drug before, and if we are unable to establish an effective sales and marketing infrastructure, we will not be able to successfully commercialize our product candidates.

In the U.S., we plan to build our own sales force to market our products directly to physicians, nurses, hospitals, group purchasing organizations and third-party payors. We currently do not have significant internal sales, distribution and marketing capabilities. In order to commercialize any of our product candidates, we must either acquire or internally develop sales and marketing capabilities, or enter into collaborations with partners to perform these services for us. The acquisition or development of a hospital-focused sales and marketing infrastructure for our domestic operations will require substantial resources, will be expensive and time consuming and could negatively impact our commercialization efforts, including delay any product launch. Moreover, we may not be able to hire a sales force that is sufficient in size or has adequate expertise. If we are unable to establish our sales and marketing capability or any other capabilities necessary to commercialize any products we may develop, we will need to contract with third parties to market and sell our products. If we are unable to establish adequate sales and marketing capabilities, whether independently or with third parties, we may not be able to generate any product revenue, may generate increased expenses and may never become profitable.

We will need to obtain FDA approval of our proposed product names, Acetavance and Omigard, and any failure or delay associated with such approval may adversely impact our business.

Any name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office. The FDA typically conducts a rigorous review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims. If the FDA objects to either of the product names Acetavance or Omigard, we may be required to adopt an alternative name for those product candidates. If we adopt an alternative name, we would lose the benefit of our existing trademark applications for Acetavance and/or Omigard and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Our product candidates may have undesirable side effects that could delay or prevent their regulatory approval or commercialization.

Undesirable side effects caused by our product candidates could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale. For example, the adverse events related to Acetavance observed in clinical trials completed to date include transient liver enzyme elevations, nausea or vomiting, allergic reactions, and pain or local skin reactions at the injection site. When used in excess of the current guidelines for administration, acetaminophen has an increased potential to cause liver toxicity. While we do not expect the administration of acetaminophen in intravenous form will result in an increased risk of toxicity to the liver compared with an equivalent dose of acetaminophen

administered orally, we cannot be certain that increased liver toxicity or other drug-related side effects will not be observed in future clinical trials or that the FDA will not require additional trials or impose more severe labeling restrictions due to liver toxicity or other concerns. Drug-related adverse events observed in clinical trials completed to date for Omigard have been primarily limited to local skin reactions, including redness, swelling, bleeding, itching, bruising and pain. In addition, while these drug-related adverse events have generally been related to the skin, including the catheter insertion site, we cannot be certain that other drug-related side effects will not be reported in clinical trials or thereafter.

If either of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by the product:

- regulatory authorities may require the addition of labeling statements, specific warnings or a contraindication;
- regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

If the government or third-party payors fail to provide coverage and adequate coverage and payment rates for our future products, if any, or if hospitals choose to use therapies that are less expensive, our revenue and prospects for profitability will be limited.

In both domestic and foreign markets, our sales of any future products will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare, managed care providers, private health insurers and other organizations. In particular, many U.S. hospitals receive a fixed reimbursement amount per procedure for certain surgeries and other treatment therapies they perform. Because this amount may not be based on the actual expenses the hospital incurs, hospitals may choose to use therapies which are less expensive when compared to our product candidates. Accordingly, Acetavance, Omigard or any other product candidates that we may in-license or acquire, if approved, will face competition from other therapies and drugs for these limited hospital financial resources. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Governments continue to propose and pass legislation designed to reduce the cost of healthcare. In the U.S., we expect that there will continue to be federal and state proposals to implement similar governmental controls. For example, in December 2003, Congress enacted a limited prescription drug benefit for Medicare beneficiaries in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Under this program, drug prices for certain prescription drugs are negotiated by drug plans, with the goal to lower costs for Medicare beneficiaries. In some foreign markets, the government controls the pricing of prescription pharmaceuticals. In these countries, pricing negotiated with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. Cost control initiatives could decrease the price that we would receive for any products in the future, which would limit our revenue and profitability. Accordingly, legislation and regulations affecting the pricing of pharmaceuticals might change before our product candidates are approved for marketing. Adoption of such legislation could further limit reimbursement for pharmaceuticals.

If we breach any of the agreements under which we license rights to our product candidates from others, we could lose the ability to continue the development and commercialization of our product candidates.

In March 2006, we entered into an exclusive license agreement with BMS relating to our Acetavance product candidate for the U.S. and Canada, and in July 2004, we entered into an exclusive license agreement with Migenix relating to our Omigard product candidate for North America and Europe. Because we have in-licensed the rights to our two product candidates from third parties, if there is any dispute between us and our licensors regarding our rights under these license agreements, our ability to develop and commercialize these product candidates may be adversely affected. Any uncured, material breach under these license agreements could result in our loss of exclusive rights to the related product candidate and may lead to a complete termination of our product development efforts for the related product candidate.

If BMS breaches the underlying agreement under which we sublicense the rights to our Acetavance product candidate, we could lose the ability to develop and commercialize Acetavance.

Our license for Acetavance is subject to the terms and conditions of a license from SCR Pharmatop to BMS, under which BMS originally licensed the intellectual property rights covering Acetavance. If BMS materially breaches the terms or conditions of this underlying license from SCR Pharmatop, and neither BMS nor we adequately cure that breach, or BMS and SCR Pharmatop otherwise become involved in a dispute, the breach by BMS or disputes with SCR Pharmatop could result in a loss of, or other material adverse impact on, our rights under our license agreement with BMS. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by BMS, and otherwise seek to preserve our rights under the patents licensed by SCR Pharmatop, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured, material breach under the license from SCR Pharmatop to BMS could result indirectly in our loss of exclusive rights to our Acetavance product candidate and may lead to a complete termination of our product development and any commercialization efforts for Acetavance.

We rely on third parties to conduct our clinical trials, including our ongoing Phase III clinical program for Acetavance and our ongoing Phase III clinical trial of Omigard. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates on our anticipated timeline or at all.

We rely primarily on third-party CROs to manage the execution of our clinical trials for our Acetavance and Omigard product candidates, and we depend on independent clinical investigators, medical institutions and contract laboratories to conduct our clinical trials. Although we rely on CROs to manage the execution of our clinical trials, we are responsible for oversight and for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA requires us and our CROs to comply with regulations and standards, commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on CROs does not relieve us of these responsibilities and requirements. CROs and investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If our CROs or independent investigators fail to devote sufficient care, time and resources to our drug development programs, if their performance is substandard, or if they are inspected by the FDA and are found not to be in compliance with GCPs, it will delay the approval of our FDA applications and our introductions of new products. The CROs with which we contract for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Failure of the CROs to meet their obligations could adversely affect clinical development of our product candidates. Moreover, these independent investigators and CROs may also have relationships with other commercial entities, some of which may have competitive products under development or currently marketed. If independent investigators and CROs assist our competitors, it could harm our competitive position. If any of these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for Acetavance, Omigard or future product candidates.

If the manufacturers upon whom we rely fail to complete required pre-commercialization manufacturing development activities on time, we may face delays in the development of, or in obtaining regulatory approvals for, our product candidates, which would result in increased costs and the loss of potential revenues.

We do not manufacture any of our product candidates, and we do not currently plan to develop any capacity to do so. Instead, we rely on third party manufacturers to perform pre-commercialization manufacturing development activities for, and manufacture, Acetavance, Omigard and, most likely, any other product candidates that we may in-license or acquire in the future. Any problems or delays we experience in preparing for commercial-scale manufacturing of a product candidate may cause us to experience increased costs, result in delays in receiving FDA or other regulatory approvals, or impair our ability to manufacture our product candidates, which would adversely affect our business. For example, as a part of our applications for regulatory approval, our manufacturers will need to produce specific batches of our product candidates to demonstrate acceptable stability under various conditions and for commercially viable lengths of time. We and our contract manufacturers will need to demonstrate to the FDA and other regulatory authorities this acceptable stability data, as well as validate methods and manufacturing processes, in order to receive regulatory approval to commercialize our product candidates. Any delays in the availability of this data may cause delays in receiving FDA or other regulatory authority approvals. Additionally, the FDA is likely to conduct inspections of our manufacturers' facilities from time to time, including as part of its review of any marketing applications we may file. If our manufacturers are not in compliance with cGMP requirements, this may delay the approval by the FDA of these marketing applications, or result in delays in the availability of our product candidates to complete clinical trials or for commercial distribution.

If the manufacturers upon whom we rely terminate our supply agreements or fail to produce our product candidates in the volumes we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our product candidates and may lose potential revenues.

If the commercial manufacturers upon whom we rely to manufacture our product candidates fail to deliver the required commercial quantities of bulk drug substance or finished product on a timely basis at commercially reasonable prices that meet all applicable quality standards, we would likely be unable to meet demand for our products and we would lose potential revenues. We have entered into a development and supply agreement with Baxter Healthcare Corporation, or Baxter, for the completion of pre-commercialization manufacturing development activities and the manufacture of commercial supplies of the finished Acetavance. Any termination or disruption of our relationship with Baxter may materially harm our business and financial condition, and frustrate any commercialization efforts for Acetavance. We do not yet have agreements established regarding commercial supply of Omigard and may not be able to establish or maintain commercial manufacturing arrangements on commercially reasonable terms for Omigard, or any other product candidates that we may in-license or acquire. We are currently negotiating with suppliers for the commercial supply of the active pharmaceutical ingredient, or API, for Acetavance and for the commercial supply of API and finished drug product for Omigard. We do not have any long-term commitments from our suppliers of clinical trial material or guaranteed prices for our product candidates or placebos, and we do not have alternate manufacturing plans in place at this time. If we need to change to other manufacturers or change the manufacturing processes for our product candidates, the FDA and comparable international regulatory authorities must approve these manufacturers' facilities and processes prior to our use, which would require new testing and compliance inspections, and the new manufacturers would have to be educated in, or independently develop, the processes necessary for the production of our products. If there are delays in obtaining approvals of any new manufacturers, we could experience delays in the availability of our product candidates to complete our clinical trials or for commercial distribution.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Our manufacturers may not perform as agreed. If our manufacturers were to encounter any of these difficulties, our ability to provide product candidates to patients in our clinical trials would be jeopardized.

In addition, all manufacturers of our product candidates must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance and the

maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any quantities supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Our future growth depends on our ability to identify and acquire or in-license products and if we do not successfully identify and acquire or in-license related product candidates or integrate them into our operations, we may have limited growth opportunities.

We in-licensed the rights to each of our two current product candidates, Acetavance and Omigard, from third parties who conducted the initial development of each product candidate. An important part of our business strategy is to continue to develop a pipeline of product candidates by acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our focus on the hospital marketplace. Future in-licenses or acquisitions, however, may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

As of January 31, 2008, we had 48 full-time employees. We will need to continue to expand our managerial, operational, financial and other resources in order to manage and fund our operations and clinical trials, continue our development activities and commercialize our product candidates. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- manage our clinical trials effectively, including our ongoing Phase III clinical program for Acetavance, which will be conducted at numerous clinical trial sites in the U.S., and our ongoing Phase III clinical trial of Omigard, which is being conducted at numerous clinical sites in the U.S. and Europe;
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- manage our internal development efforts effectively while carrying out our contractual obligations to licensors and other third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our development and commercialization goals.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Diego, California area. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the product acquisition, development, regulatory and commercialization expertise of our senior management, particularly Theodore R. Schroeder, our President and Chief Executive Officer, James B. Breitmeyer, M.D., Ph.D., our Executive Vice President, Development and Chief Medical Officer, and William R. LaRue, our Senior Vice President, Chief Financial Officer, Treasurer and Assistant Secretary. If we lose one or more of these key employees, our ability to successfully implement our business strategy could be seriously harmed. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel. Although we have employment agreements with Mr. Schroeder, Dr. Breitmeyer and Mr. LaRue, these agreements are terminable at will at any time with or without notice and, therefore, we may not be able to retain their services as expected.

In addition, we have scientific and clinical advisors who assist us in our product development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
 - termination of clinical trial sites or entire trial programs;
 - decreased demand for our product candidates;
 - impairment of our business reputation;
 - costs of related litigation;
 - substantial monetary awards to patients or other claimants;
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- loss of revenues; and
- the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our clinical trials with a \$15.0 million annual aggregate coverage limit and additional amounts in selected foreign countries where we are conducting clinical trials. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Recent proposed legislation may permit re-importation of drugs from foreign countries into the U.S., including foreign countries where the drugs are sold at lower prices than in the U.S., which could materially adversely affect our operating results and our overall financial condition.

Legislation has been introduced in Congress that, if enacted, would permit more widespread re-importation of drugs from foreign countries into the U.S., which may include re-importation from foreign countries where the drugs are sold at lower prices than in the U.S. Such legislation, or similar regulatory changes, could decrease the price we receive for any approved products which, in turn, could materially adversely affect our operating results and our overall financial condition. For example, BMS markets Acetavance in Europe and other countries principally under the brand name Perfalgan. Although Perfalgan is not labeled for sale in the U.S. and we have an exclusive license from BMS and its licensor to develop and sell Acetavance in the U.S., it is possible that hospitals and other users may in the future seek to import Perfalgan rather than purchase Acetavance in the U.S. for cost-savings or other reasons. We would not receive any revenues from the importation and sale of Perfalgan into the U.S.

Our business involves the use of hazardous materials and we and our third-party manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our third-party manufacturers' activities and, to a lesser extent, our own activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state or federal authorities may curtail our use of these materials and interrupt our business operations.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for Acetavance or Omigard could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidates may be delayed.

Risks Related to Intellectual Property

The patent rights that we have in-licensed covering Acetavance are limited to a specific intravenous formulation of acetaminophen, and our market opportunity for this product candidate may be limited by the lack of patent protection for the active ingredient itself and other formulations that may be developed by competitors.

The active ingredient in Acetavance is acetaminophen. Patent protection for the acetaminophen molecule itself in the territories licensed to us, which include the U.S. and Canada, is not available. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredient as Acetavance so long as the competitors do not infringe any process or formulation patents that we have in-licensed from BMS and its licensor, SCR Pharmatop. We are aware of a number of third-party patents in the U.S. that claim methods of making acetaminophen. If a supplier of the API for our Acetavance product candidate is found to infringe any of these method patents covering acetaminophen, our supply of the API could be delayed and we may be required to locate an alternative supplier. We are also aware of several U.S. and Canadian patents and patent applications covering various potential injectable formulations of acetaminophen as well as methods of making and using these potential formulations. For example, Injectapap, a liquid formulation of acetaminophen for intramuscular injection was approved by the FDA for the reduction of fever in adults in March 1986, although it was subsequently withdrawn from the market by McNeil Pharmaceutical in July 1986.

The number of patents and patent applications covering products in the same field as Acetavance indicates that competitors have sought to develop and may seek to market competing formulations that may not be covered by our licensed patents and patent applications. In addition, the Canadian patent applications that we have in-licensed have yet to be examined by the Canadian Patent Office. Thus, they may issue with claims that cover less than the corresponding in-licensed U.S. patents, or simply not issue at all. The commercial opportunity for our Acetavance product candidate could be significantly harmed if competitors are able to develop an alternative formulation of acetaminophen outside the scope of our in-licensed patents.

The patent rights that we have in-licensed covering Omigard are limited in scope and limited to specific territories.

We have an exclusive license from Migenix for Omigard in North America and Europe for the licensed field, although currently there are issued patents only in the U.S. and certain European countries. Canadian applications are pending; however, the claims that ultimately issue in Canada may be narrower than the protection obtained in the U.S. and Europe or may simply not issue at all. In addition, no patent protection has been sought in Mexico. Accordingly, the manufacture, sale and use of Omigard in Mexico by a competitor cannot be prevented. Furthermore, there are third-party patents covering analogs of omiganan and Migenix has patented analogs of omiganan that are not licensed to us. It is possible that competitors having rights to these patents may develop competing products having the same, similar or better efficacy compared to Omigard.

Furthermore, our license agreement with Migenix may be construed to cover only the use of Omigard and other formulations of omiganan for the licensed field, which is the topical administration to a burn or a surgical wound site for the treatment of burn-related, surgical wound-related infections and the topical administration to a device or the site around the device for the treatment of device-related infections. Thus, Migenix or third-party licensees of Migenix may be able to market Omigard for other uses, including treatment of non-surgery related wound infections. We may be unable to prevent physicians from using any such competitive Omigard product off-label for the field licensed to us.

We depend on our licensors for the maintenance and enforcement of our intellectual property and have limited control, if any, over the amount or timing of resources that our licensors devote on our behalf.

We depend on our licensors, BMS, SCR Pharmatop, and Migenix, to protect the proprietary rights covering Acetavance and Omigard. Regarding Acetavance, either BMS or its licensor, SCR Pharmatop, depending on the patent or application, is responsible for maintaining issued patents and prosecuting patent applications. Regarding Omigard, Migenix is responsible for maintaining issued patents and prosecuting patent applications. We have limited, if any, control over the amount or timing of resources that our licensors devote on our behalf or the priority they place on maintaining these patent rights and prosecuting these patent applications to our advantage. SCR Pharmatop is under a contractual obligation to BMS to diligently prosecute their patent applications and allow BMS the opportunity to consult, review and comment on patent office communications. However, we cannot be sure that SCR Pharmatop will perform as required. Should BMS decide it no longer wants to maintain any of the patents

licensed to us, BMS is required to afford us the opportunity to do so at our expense. However, we cannot be sure that BMS will perform as required. If BMS does not perform, and if we do not assume the maintenance of the licensed patents in sufficient time to make required payments or filings with the appropriate governmental agencies, we risk losing the benefit of all or some of those patent rights. For patents and applications licensed from Migenix, Migenix is obligated to use commercially reasonable efforts to obtain and maintain patent rights covering Omigard in North America and Europe. If Migenix intends to abandon prosecution or maintenance of any patents or applications, they are obligated to notify us, and at that time, we will be granted an opportunity to maintain and prosecute the patents and applications at our expense. In such a case, Migenix is required to transfer all necessary rights and responsibilities to facilitate our maintenance and prosecution of the patents and applications. Similar to BMS, however, we cannot be certain that Migenix will perform its contractual obligations as required or that we will be able to adequately assume the prosecution or maintenance of the Omigard-related patents and applications.

As part of a financing transaction, Migenix has pledged as collateral to its lenders the patents and patent applications covering Omigard. While we believe our license agreement with Migenix would survive any foreclosure on these patents and patent applications, we cannot be sure that the lenders will have adequate expertise or resources to properly perform Migenix' obligations to us under the license agreement, including maintaining and prosecuting the patents and patent applications.

While we intend to take actions reasonably necessary to enforce our patent rights, we depend, in part, on our licensors to protect a substantial portion of our proprietary rights. In the case of the Acetavance patents, BMS has the first right to prosecute a third-party infringement of the SCR Pharmatop patents, and has the sole right to prosecute third-party infringement of the BMS patents. We will have the ability to cooperate with BMS in third-party infringement suits involving the SCR Pharmatop patents. It is possible that SCR Pharmatop or BMS could take some action or fail to take some action that could harm the SCR Pharmatop patents. In certain instances, we may be allowed to pursue the infringement claim ourselves. With respect to Omigard, we have the first right to prosecute a third-party for infringement of the in-licensed Migenix patents provided the infringing activities are in North America or Europe and relate primarily to the licensed field of use. Migenix is obligated to reasonably cooperate with any such suit.

Our licensors may also be notified of alleged infringement and be sued for infringement of third-party patents or other proprietary rights. We may have limited, if any, control or involvement over the defense of these claims, and our licensors could be subject to injunctions and temporary or permanent exclusionary orders in the U.S. or other countries. Our licensors are not obligated to defend or assist in our defense against third-party claims of infringement. We have limited, if any, control over the amount or timing of resources, if any, that our licensors devote on our behalf or the priority they place on defense of such third-party claims of infringement. Finally, Migenix is not obligated to defend or assist in our defense of a third-party infringement suit relating to our Omigard product candidate; however, Migenix has the right to control the defense and settlement that relates to the validity and enforceability of claims in the in-licensed Migenix patents.

For a third-party challenge to the SCR Pharmatop in-licensed patents relating to Acetavance, we will have some ability to participate in either SCR Pharmatop's or BMS' defense thereof. In the case that neither party elects to defend the third-party challenge, we may have the opportunity to defend it. For a third-party challenge to the in-licensed BMS patents relating to Acetavance, BMS has the sole right to defend such challenge. If it chooses not to, we may have the right to renegotiate or terminate the license regarding the in-licensed BMS patents.

Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we or our licensors may not be successful in defending claims of intellectual property infringement by third parties, which could have a material adverse affect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management.

Because it is difficult and costly to protect our proprietary rights, we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for Acetavance, Omigard or any other product candidates that we may in-license or acquire and the methods we use to manufacture them, as well as successfully defending these patents against third-party challenges. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the U.S. The patent situation outside the U.S. is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our product candidates or technologies;
- it is possible that none of the pending patent applications licensed to us will result in issued patents;
- the issued patents covering our product candidates may not provide a basis for commercially viable active products, may not provide us with any competitive advantages, or may be challenged by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- patents of others may have an adverse effect on our business.

Patent applications in the U.S. are maintained in confidence for at least 18 months after their earliest effective filing date. Consequently, we cannot be certain that our licensors were the first to invent or the first to file patent applications on some of our product candidates. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention in the U.S. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. Furthermore, we may not have identified all U.S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

In addition, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect our product candidates. Even if patents issue, we cannot guarantee that the claims of those patents will be valid and enforceable or provide us with any significant protection against competitive products, or otherwise be commercially valuable to us.

We also rely on trade secrets to protect our technology, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our licensors, employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If our licensors or we fail to obtain or maintain patent protection or trade secret protection for Acetavance, Omigard or any other product candidate we may in-license or acquire, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business.

Our ability to develop, manufacture, market and sell Acetavance, Omigard or any other product candidates that we may in-license or acquire depends upon our ability to avoid infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the general fields of pain treatment and prevention of infections and cover the use of numerous compounds and formulations in our targeted markets. For instance, there is a patent in force in various European countries, with claims that, if valid, may be broad enough in scope to cover the formulation of our Omigard product candidate. It is possible that we may determine it prudent to seek a license to this European patent in order to avoid potential litigation and other disputes. We cannot be sure that a license would be available to us on commercially reasonable terms, or at all. Similarly, there is a patent application pending in the U.S. that corresponds to the European patent. Because this patent application has neither published nor issued, it is too early to tell if the claims of this application will present similar issues for Omigard in the U.S. There is also a patent application pending in Canada that corresponds to the European patent. Because this patent application has not issued, it is too early to tell if the claims of this application will present similar issues for Omigard in Canada. However, similar to the European patent, if the U.S. or Canadian patent applications issue with a scope that is broad enough to cover our Omigard product candidate and we are unable to assert successful defenses to any patent claims, we may be unable to commercialize Omigard, or may be required to expend substantial sums to obtain a license to the other party's patent. While we believe there may be multiple grounds to challenge the validity of the European patent, and these grounds may be applicable to the U.S. and Canadian applications should they issue as patents, the outcome of any litigation relating to this European patent and the U.S. and Canadian patent applications, or any other patents or patent applications, is uncertain and participating in such litigation would be expensive, time-consuming and distracting to management. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and Migenix may not be successful in defending intellectual property claims by third parties, which could have a material adverse affect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that Acetavance or Omigard may infringe. There could also be existing patents of which we are not aware that Acetavance or Omigard may inadvertently infringe.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we infringe on their products or technology, we could face a number of issues, including:

- infringement and other intellectual property claims which, with or without merit, can be expensive and time consuming to litigate and can divert management's attention from our core business;
 - substantial damages for past infringement which we may have to pay if a court decides that our product infringes on a competitor's patent;
 - a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it is not required to do;
 - if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
 - redesigning our processes so they do not infringe, which may not be possible or could require substantial funds and time.
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We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Finances and Capital Requirements

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

We are a development stage company with a limited operating history. We have focused primarily on in-licensing and developing our two product candidates, Acetavance and Omigard, with the goal of supporting regulatory approval for these product candidates. We have incurred losses in each year since our inception in May 2004. Net losses were \$52.2 million and \$7.7 million for the years ended December 31, 2006 and 2005, respectively. As of September 30, 2007, we had an accumulated deficit of \$100.2 million. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect our development expenses as well as clinical product manufacturing expenses to increase in connection with our ongoing and planned Phase III clinical trials and any additional clinical trials that we may be required to conduct in order to support regulatory approvals, additional indications or dosages for our product candidates. In addition, if we obtain regulatory approval for Acetavance or Omigard, we expect to incur significant sales, marketing and outsourced manufacturing expenses as well as continued development expenses. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We currently have no source of revenue and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our development stage product candidates, and we do not know when, or if, we will generate any revenue. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete our ongoing and future clinical trials for Acetavance and Omigard;
- obtain regulatory approval for either of our two product candidates or any other product candidate that we may in-license or acquire;
- assuming these regulatory approvals are received, manufacture commercial quantities of our product candidates at acceptable cost levels; and
- successfully market and sell any approved products.

Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product. We also do not anticipate that we will achieve profitability for at least several years after generating material revenues, if ever. If we are unable to generate revenues, we will not become profitable and may be unable to continue operations without continued funding.

Our short operating history makes it difficult to evaluate our business and prospects.

We were incorporated in May 2004 and have only been conducting operations with respect to our Acetavance product candidate since March 2006 and our Omigard product candidate since July 2004. Our operations to date have been limited to organizing and staffing our company, in-licensing our two product candidates and conducting product development activities, including clinical trials and manufacturing development activities, for our two product candidates. We have not yet demonstrated an ability to obtain regulatory approval for or successfully commercialize a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

We will need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing products for use in the hospital setting, conducting clinical trials, establishing outsourced manufacturing relationships and successfully manufacturing and marketing drugs that we may develop is expensive. We will need to raise additional capital to:

- fund our operations and continue to conduct adequate and well-controlled clinical trials to provide clinical data to support regulatory approval of marketing applications;
- continue our development activities;
- qualify and outsource the commercial-scale manufacturing of our products under cGMP; and
- commercialize Acetavance, Omigard or any other product candidates that we may in-license or acquire, if any of these product candidates receive regulatory approval.

We believe that our existing cash and cash equivalents, including the net proceeds from our initial public offering completed in the fourth quarter of 2006, will be sufficient to meet our projected operating requirements, at a minimum, through June 30, 2008. We have based this estimate on assumptions that may prove to be wrong and we could spend our available financial resources faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and cost of our clinical trials and other product development programs for Acetavance, Omigard and any other product candidates that we may in-license or acquire;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- the cost and timing of completion of an outsourced commercial manufacturing supply for each product candidate;
- the costs and timing of regulatory approval;
- the costs of establishing sales, marketing and distribution capabilities;
- the effect of competing technological and market developments; and
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies, but we currently have no commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash and investment balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- the timing of milestone payments required under our license agreements for Acetavance and Omigard;
- our execution of other collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- our addition or termination of clinical trials or funding support;
- variations in the level of expenses related to our two existing product candidates or future development programs;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our product candidates or those of our competitors; and
- if either of our product candidates receives regulatory approval, the level of underlying hospital demand for our product candidates and wholesalers' buying patterns.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Raising additional funds by issuing securities may cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. If we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. For example, in February 2006, we entered into a \$7.0 million loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation, and in December 2007, we amended this agreement to secure an additional \$15.0 million loan from the same parties and Merrill Lynch Capital. These loan and security agreements contain a variety of affirmative and negative covenants, including required financial reporting, limitations on the disposition of assets other than in the ordinary course of business, limitations on the incurrence of additional debt and other requirements. To secure our performance of our obligations under the loan and security agreement, we pledged substantially all of our assets other than intellectual property assets, to the lenders. Our failure to comply with the covenants in the loan and security agreement could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt.

We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and The NASDAQ Stock Market LLC. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more

expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, commencing in fiscal 2007, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

Risks Relating to Securities Markets and Investment in Our Stock

There may not be a viable public market for our common stock.

Our common stock had not been publicly traded prior to our initial public offering, which was completed in October 2006, and an active trading market may not develop or be sustained. We have never declared or paid any cash dividends on our capital stock, and we currently intend to retain all available funds and any future earnings to support operations and finance the growth and development of our business and do not intend to pay cash dividends on our common stock for the foreseeable future. Furthermore, our loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation restricts our ability to pay cash dividends. Therefore, investors will have to rely on appreciation in our stock price and a liquid trading market in order to achieve a gain on their investment. The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Since our initial public offering in October 2006 through January 31, 2008, the trading prices for our common stock ranged from a high of \$18.55 to a low of \$5.01.

Future sales of our common stock may cause our stock price to decline.

Persons who were our stockholders prior to the sale of shares in our initial public offering continue to hold a substantial number of shares of our common stock that they may now be able to sell in the public market. Significant portions of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. Moreover, the holders of a substantial number of shares of common stock may have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders.

We have also registered all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws. In addition, our directors and executive officers may in the future establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

We expect that the price of our common stock will fluctuate substantially.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- the results from our clinical trial programs, including our ongoing Phase III clinical program for Acetavance and our ongoing Phase III clinical trial of Omigard;
- the results of clinical trial programs for Acetavance and Omigard being performed by others;
- FDA or international regulatory actions, including failure to receive regulatory approval for any of our product candidates;
- failure of any of our product candidates, if approved, to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- developments concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- actual and anticipated fluctuations in our quarterly operating results;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- third-party coverage and reimbursement policies;
- developments concerning current or future strategic collaborations; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

The realization of any of the risks described in these “Risk Factors” could have a dramatic and material adverse impact on the market price of our common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs and a diversion of management’s attention and resources, which could hurt our business, operating results and financial condition.

Our executive officers and directors and their affiliates may exercise control over stockholder voting matters in a manner that may not be in the best interests of all of our stockholders.

As of September 30, 2007, our executive officers and directors and their affiliates together controlled approximately 41% of our outstanding common stock. As a result, these stockholders will collectively be able to significantly influence all matters requiring approval of our stockholders, including the election of directors and approval of significant corporate transactions. The concentration of ownership may delay, prevent or deter a change in control of our company even when such a change may be in the best interests of all stockholders, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets, and might affect the prevailing market price of our common stock.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
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- a prohibition on stockholder action through written consent;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations;
- a requirement of approval of not less than 66 2/3% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors, including to delay or impede a merger, tender offer or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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

We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Furthermore, our loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation restricts our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.