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): January 12, 2009

CADENCE PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-33103**	**41-2142317**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

12481 High Bluff Drive, Suite 200, San Diego, California	**92130**
(Address of Principal Executive Offices)	**(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))

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 at various investor and analyst meetings in San Francisco during the week beginning January 12, 2009.

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.*

Exhibit Number	Description of Exhibit
99.1	Company Slides – dated January 12, 2009
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: January 12, 2009

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

Exhibit Number	Description of Exhibit
99.1	Company Slides – dated January 12, 2009
99.2	Risk Factors

Exhibit 99.1

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Corporate Overview

January 2009

Improving the lives of hospitalized patients

Theodore R. Schroeder

President, CEO & Co-Founder

Forward-looking statements

This presentation includes forward-looking statements. Words such as “believes,” “plans,” “expects,” “anticipates,” and “will” are intended to identify forward-looking statements, and are based on our current beliefs and expectations. They include statements regarding: our belief that we have completed the clinical development program for Acetavance, the potential results of the ongoing review of Phase 3 clinical trial data for Omigard, the timeframes in which we expect to submit NDAs for our product candidates, the anticipated clinical efficacy, safety, labeling claims, medical need, pricing, market potential and the availability of adequate patent and regulatory exclusivity protection for our product candidates.

Our actual results may differ materially from those included in this presentation due to the risks and uncertainties inherent in our business, such as: the FDA may require us to complete additional trials, testing or other requirements prior to submitting NDAs for our product candidates; final analyses of data from our clinical trials may vary from initial analyses; the FDA may not agree with our interpretation of the results of our clinical trials; our clinical trials may produce negative or inconclusive results, or may be inconsistent with previously conducted clinical trials; we expect intense competition and pricing pressure for our product candidates, and new products may emerge that provide different or better therapeutic alternatives; the FDA may not agree with changes we have proposed in the statistical analysis plan for our Phase 3 clinical trial of Omigard, and we cannot be certain how the FDA will analyze the results of the trial; our clinical trial data may not indicate sufficient therapeutic efficacy for our product candidates, and these data or adverse event reporting data from countries where Acetavance is approved, may indicate that adverse side effects are more prevalent or severe than anticipated; we may experience delays in completing important manufacturing development activities, which would delay our NDA submissions; the performance of third parties on whom we rely to complete key development activities may be substandard, late, or may be of insufficient quality to include in our NDAs; we may require substantial additional funding to complete our development programs and, if approved, to launch our product candidates, and we may not be able to raise sufficient capital when needed, or at all. These and other risks are detailed in our prior press releases and periodic public filings with the Securities and Exchange Commission, and we encourage you to read them carefully. 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, which is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995, and we undertake no obligation to revise or update this presentation to reflect events or circumstances after the date hereof.

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)**
  - EU market leader; significant US market opportunity
  - Opioid-sparing potential
  - Pivotal efficacy trials completed – 505(b)(2) NDA submission expected 2Q09

- **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
  - Phase III results expected 1Q09

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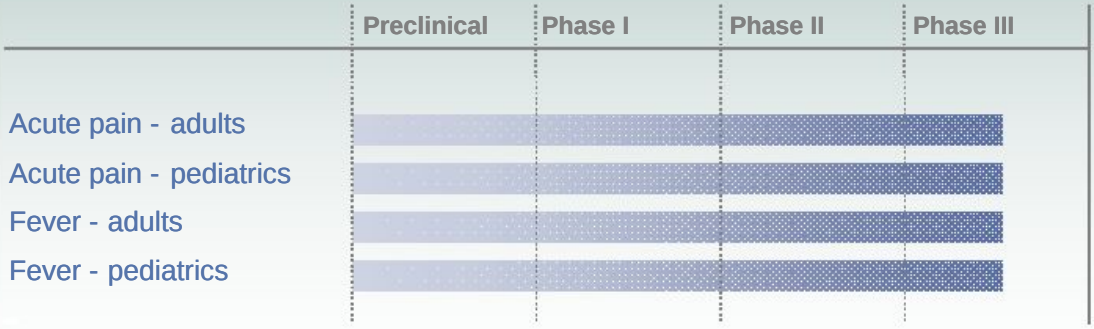
Acetavance™

intravenous acetaminophen



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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 other medications

- **Acetavance – proprietary IV formulation**

  Marketed by BMS in Europe since 2002 (Perfalgan™)

  Cadence acquired US and Canadian rights from BMS

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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

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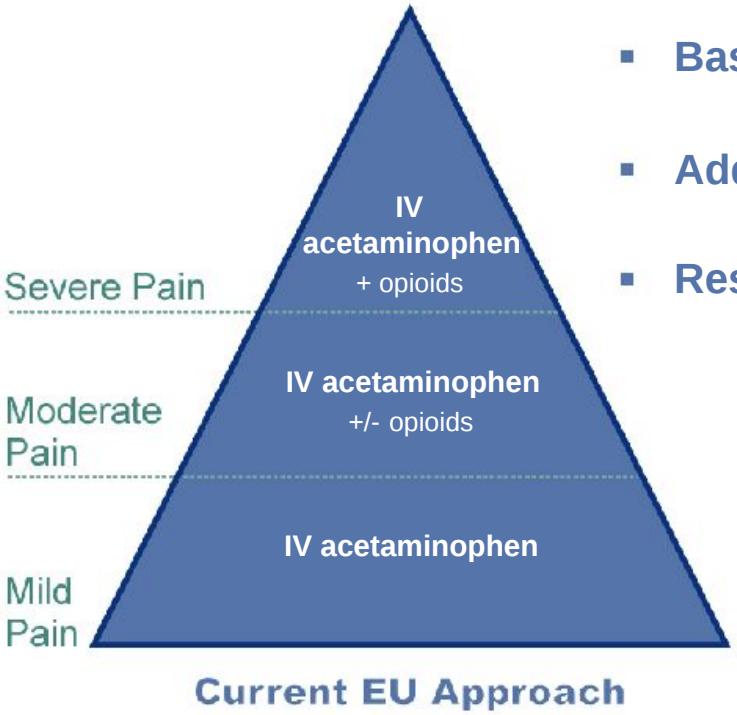
Acetavance™: foundation of multi-modal analgesia



Current EU Approach

- **Baseline analgesic post-op**
- **Add opioids if pain increases**
- **Result[1]:**
  - >33% decrease in opioids
  - Superior pain relief
  - Better patient satisfaction

[1] Sinatra, et al. Anesthesiology. April 2005

Acetavance™: IV acetaminophen leads EU market

European IV Acetaminophen Sales

Source: IMS data, company estimates

Acetavance™: IV acetaminophen leads EU market

EU IV Acetaminophen Sales Performance

	Launch Date	2007 Unit Share*
	Jun 02	47%
	Nov 02	17%
	Jun 03	22%
	Apr 04	27%
	Dec 04	8%
	Mar 04	20%
	Total EU market	**21%**

Source: IMS data

* Unit share of all injectable analgesics

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Acetavance™: large US market opportunity

- US and EU injectable analgesics markets are similarly sized
- ~80 million IV acetaminophen units sold in Europe in 2007
- $8-10 US price expected for Acetavance

Sources: IMS data, company estimates

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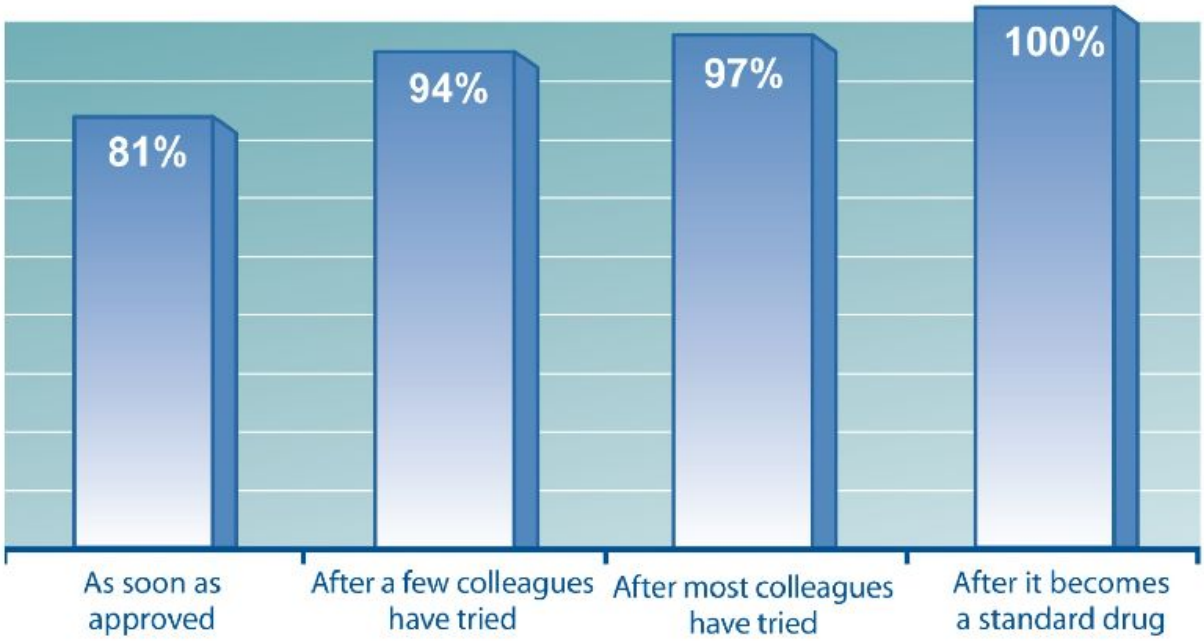
Acetavance™: significant physician support

- **Market survey of 126 US physicians suggests readiness to adopt**



Source: IMS market research 2007

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Acetavance™: clear path to NDA

- **505(b)(2) NDA**
  - Reformulation of one of the most widely used drugs in the US
  - Ability to reference studies conducted by others, including extensive literature
- **Safety**
  - Safety consistent with placebo, including hepatic safety
  - >2,000 subjects studied in clinical trials
  - >300 million doses sold outside of the US
- **Efficacy**
  - 2 required pivotal trials successfully completed
  - >10 other successful studies for treatment of pain and fever

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Acetavance™: FDA agreed upon NDA requirements

Study	n	Design	Result
Adult Efficacy			
Sinatra Study	101	Hip/knee replacement	SPID24 p<0.001
Study 302	60	Endotoxin-induced fever	WSTD6 p<0.001
Adult Safety & PK			
Study 301	332	Abdominal GYN surgery	Safety comparable to placebo over 48h
Study 351	>50	5-day safety	Safety comparable to standard of care
Study 101	38	PK vs. oral acetaminophen	Demonstrated lack of accumulation over 48h
Pediatric Safety & PK			
Study 102	75	Pharmacokinetics	PK comparable to adults Age-related reduction in clearance in newborns
Study 352	>50	5-day safety	Enrollment complete Topline results available 1Q09

SPID24: sum of pain intensity differences over 24hrs
WSTD6: weighted sum of temperature differences over 6hrs

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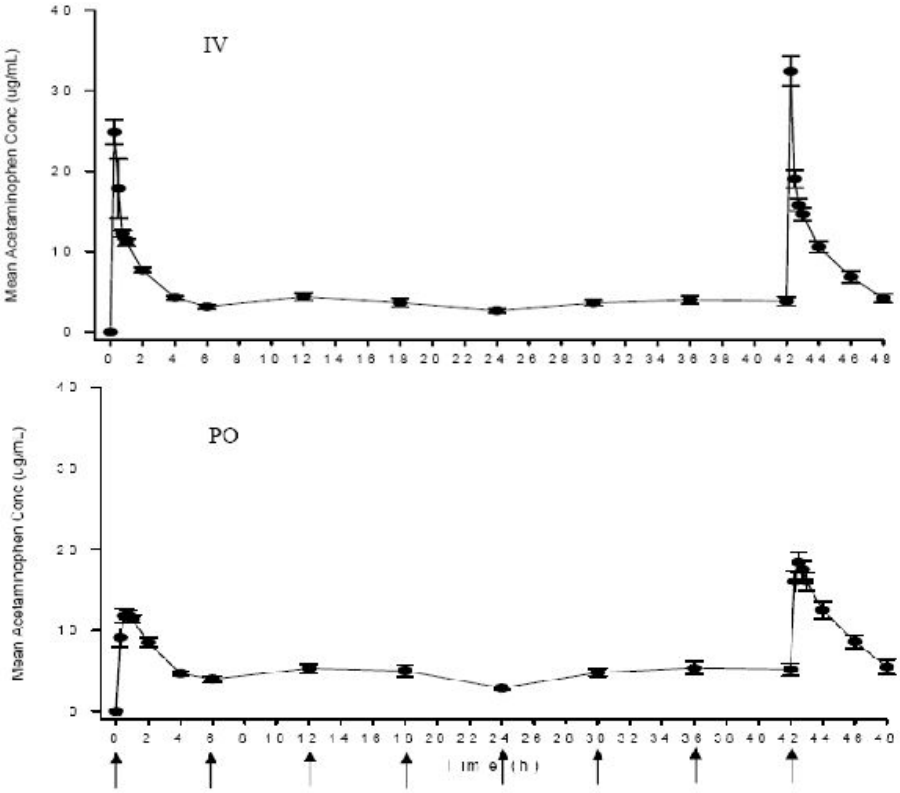
Acetavance™: no accumulation over 48 hours

Study 101: PK study comparing IV to oral acetaminophen (n=38)



Mean acetaminophen concentration over time profiles for each treatment six hour IV or PO dosing regimen

Arrow (dosing time), error bar (standard error), solid dot and line (arithmetic mean acetaminophen concentration)

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Acetavance™: hepatic safety similar to placebo

Summary of ALT/AST Treatment-Emergent Events

	Subjects with Treatment-Emergent ALT/AST Elevations*	
	Acetavance	Placebo
Single dose studies	3.1% (12/381)	8.2% (12/146)
Multiple dose studies	3.0% (8/268)	5.2% (14/269)
TOTAL	3.1% (20/649)	6.3% (26/415)

* AE reports are regardless of relatedness and majority were assessed by investigator to be unrelated to study drug

* ALT = serum alanine aminotranferase; AST = serum aspartate aminotransferase

Source: Poster presentation, American Society of Regional Anesthesia and Pain Medicine, May 2008, Cancun, Mexico.

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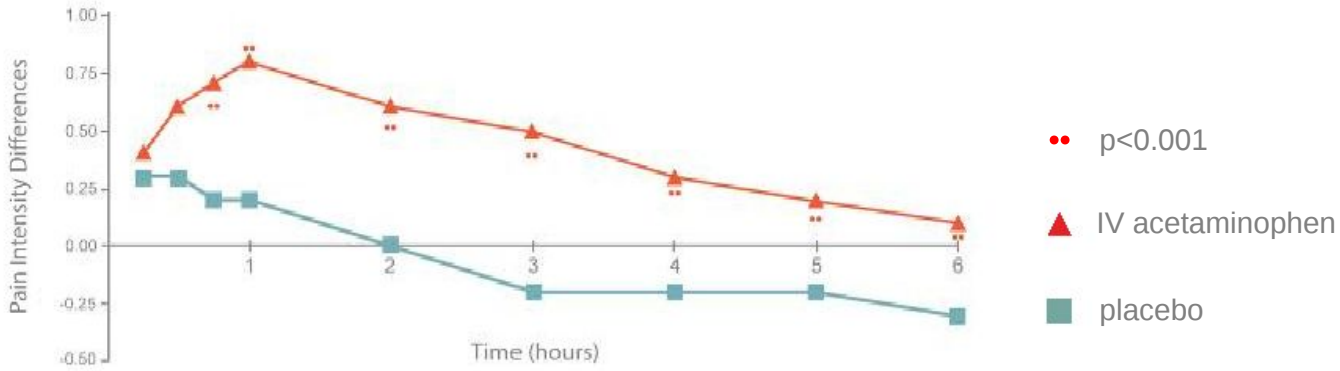
Acetavance™: pivotal study in post-op pain

Sinatra Study: Placebo-controlled, total hip & total knee replacement *(n=49/52)*



	IV acetaminophen	placebo	p-value
Sum of pain intensity difference over 24h	0.4	-235	<0.0001
Weighted sums of pain relief over 6h	6.6	2.2	<0.05
Good/excellent evaluation at 24h	41%	23%	<0.01
Morphine consumption	38.3 mg (33% ↓)	57.4 mg	<0.01
Safety	IV acetaminophen not different than placebo		

Sinatra, et al. Anesthesiology, V 102, No. 4, April 2005.

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Acetavance™: pivotal study in fever

Study 302: Placebo-controlled, endotoxin-induced fever *(n=60)*

	IV acetaminophen	placebo	p-value
Primary endpoint: WSTD6			
Mean (SD)	-3.7 (3.58)	-0.7 (3.32)	0.001
Median	-3.7	-1.2	
Range	-9.8 to 5.5	-10.0 to 8.2	
Secondary endpoints			
WSTD3	-0.9	0.7	<0.0001
Max temp reduction T0 to T6h	1.3	0.9	<0.05
% subjects w/ temp <38°C T0 to T6h	42%	10%	<0.01

WSTD6: weighted sum of temperature differences over 6 hours

WSTD3: weighted sum of temperature differences over 3 hours

Acetavance™: supportive efficacy trials

Additional placebo-controlled efficacy trials supporting 505(b)(2) NDA

Study	n	Design	Result
Study 304	240	Abdominal laparoscopy	SPID24 p<0.01
Study 303	81	Endotoxin-induced fever	WSTD2 p=0.0039
136-01-03 (BMS)	69	Hip replacement	PID at 1, 2, 3 and 4 hrs p<0.001
136-02-03 (BMS)	61	Hip replacement	PID at 1, 2, and 3 hrs p<0.05
136-03-03 (BMS)	44	Hip replacement	PID at 1, 2, and 3 hrs p<0.05
Moller et al	152	Oral surgery	Mean PR through 6 hrs p=0.0001
Cattabriga et al	113	Cardiac surgery w/ median sternotomy	PI at 24 hrs p=0.0044
Atef et al	76	Tonsillectomy	Rescue med consumption p<0.001
Juhl et al	297	Oral surgery	TOTPAR6 p < 0.0001
Kemppainen et al	74	Endoscopic sinus surgery	Rescue med consumption p=0.001

SPID24: sum of pain intensity differences over 24hrs
WSTD2: weighted sum of temperature differences over 2hrs

PI: pain intensity
PID: pain intensity difference
TOTPAR6: total pain relief over 6hrs

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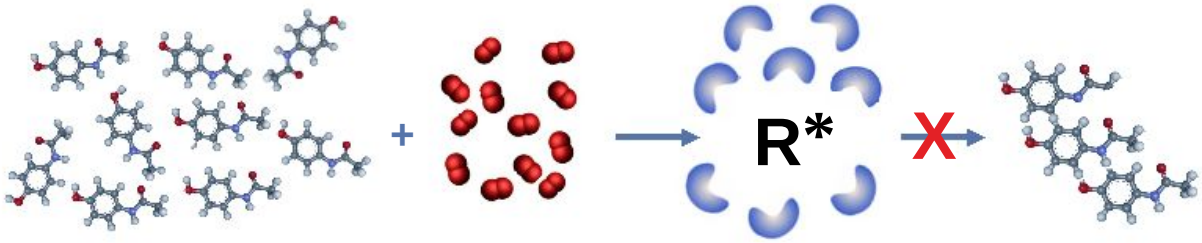
Acetavance™: strong intellectual property

Formulation must protect acetaminophen from O_2 degradation



Acetaminophen in solution | Oxygen | Free radical formation | Acetaminophen polymers

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 acetaminophen formulations containing radical scavengers and/or radical antagonists
- Expires in 2017

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Omigard™

omiganan 1% aqueous gel

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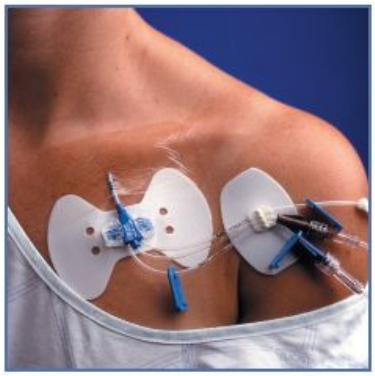
Omigard™: product overview

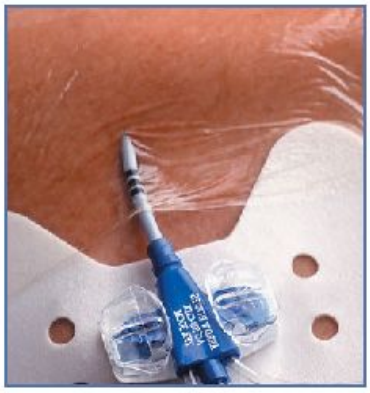
Cadence acquired North American and European rights

- **Topical antimicrobial for catheter-related infections**
  - Bactericidal *and* fungicidal
  - Rapid *and* prolonged effect
- **No acquired resistance observed**
- **Excellent safety profile**
- **Convenient application**

Omigard™: significant unmet need

- **Catheters are leading cause of BSI**
  - 325,000 catheter-related BSIs annually
  - 40,000 - 80,000 deaths
- **Mounting pressure 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





Source: Centers for Disease Control

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Omigard™: large market opportunity

- **20 million central lines placed in US annually**
  - 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 annually**

Source: Theta Report 2007, company estimates

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Omigard™: clinical development plan

- **Special Protocol Assessment (SPA) 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**

  Reached patient enrollment goal of 1,850 in the US and Europe

  Additional Evaluation Committee review ongoing

  Topline results expected 1Q09

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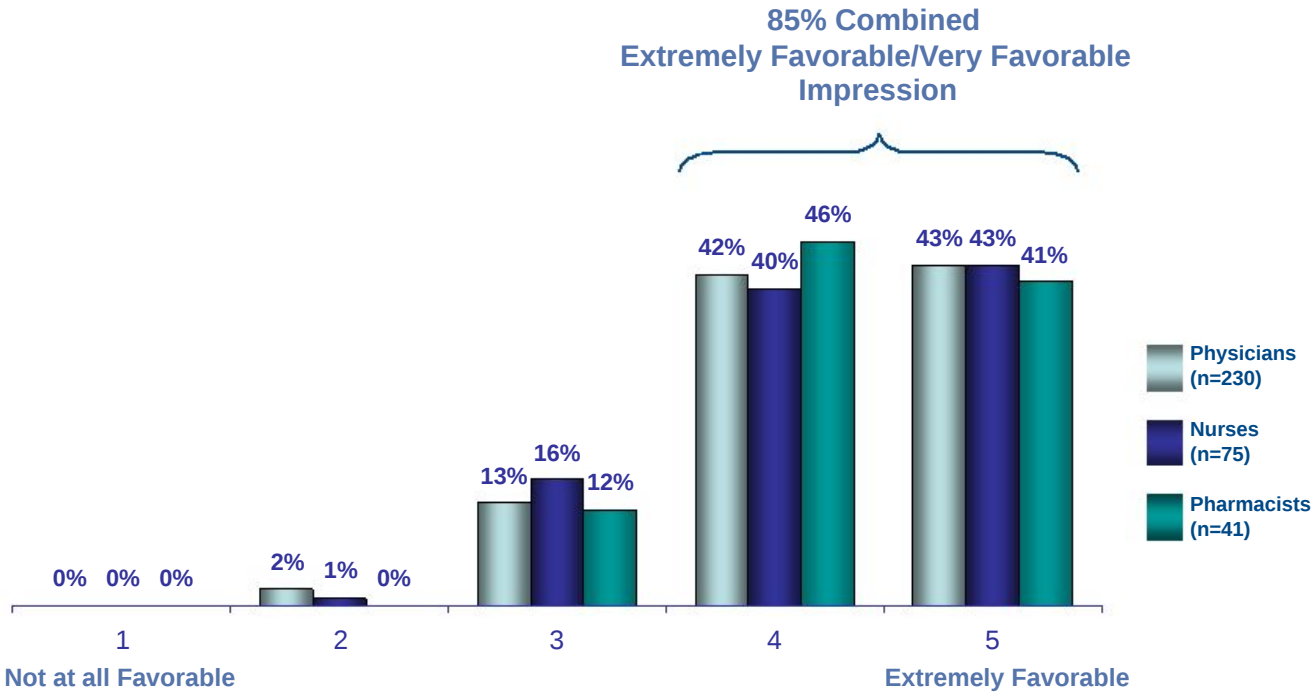
Omigard™: perceived as major advancement



Harris Interactive, Inc. November 2006

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Cadence: key milestones

- Omigard Phase III CLIRS results 1Q09
- Acetavance NDA submission 2Q09
- Omigard NDA submission 2Q09

Cadence: financial position

	12 Months Ended 12/31/07 (MM)	9 Months Ended 9/30/08 (MM)
Operating expenses	$54.2	$42.9
Cash and cash equivalents (1)	$55.4	$61.1
Shares outstanding (1)	29.1	38.4

(1) Results for 9 Months Ended 9/30/08 include net proceeds of approx. $49.1 million from a registered direct offering of approx. 9.2 million shares of common stock completed in February 2008

Cadence: highlights

Acetavance™

- **Clear path to 505(b)(2) NDA**
  - Pivotal efficacy trials complete
  - New data support safety profile
  - Reformulation of most widely used pain drug in US
- **Significant US market opportunity**
  - #1 injectable pain drug in Europe
  - Pricing upside in US vs. Europe

Omigard™

- **SPA path to NDA**
  - Enrollment complete in confirmatory Phase III trial
- **Large unmet need**
  - Impact on patient care and cost to hospitals

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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, 2007, in its entirety, as well as our other public filings with the U.S. 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 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;*
- *the outcomes 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;*
- *our 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 perform additional analyses, collect more data, or conduct additional clinical trials in order to obtain regulatory approvals;*
- *if quality issues arise during the completion of required pre-commercialization manufacturing development activities for our product candidates, or if changes are made in scaling-up the manufacturing processes for our product candidates that result in a lack of comparability between our commercial products and the products tested in our clinical trials, we may be required to perform additional non-clinical or clinical studies, which would cause delays in or limit our ability to obtain regulatory approvals, increase our costs, and result in the loss of potential revenues;*
- *if our third party manufacturers fail to complete important pre-commercialization manufacturing development activities for our product candidates on a timely basis, including the completion of batches of our product candidates that are required to perform stability studies, or if they fail to comply with stringent regulations applicable to pharmaceutical manufacturers, our costs will increase and we will face delays in our ability to submit applications for regulatory approval of our product candidates;*
- *unexpected adverse side effects or inadequate therapeutic efficacy of Acetavance or Omigard could delay the submission of applications for, or prevent the regulatory approval or commercialization of, our product candidates, or result in recalls or product liability claims against us;*
- *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;*
- *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 may not be able to maintain patent protection for our products and to commercialize our products without infringing the patent rights of others; and*
- *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.*

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. or in other countries until we receive marketing approval from the appropriate regulatory authorities. 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. The FDA has significant discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA may find that data from pre-clinical studies or clinical trials of a product candidate do not provide adequate assurance of its safety and efficacy. The FDA may also not approve the facilities or manufacturing processes used to produce the drug, or may require a company to perform substantial additional pre-clinical, clinical or manufacturing development work prior to granting approval. Additionally, the FDA may change its approval policies or adopt new regulations at any time.

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. Later in 2006, we initiated our development program for this product candidate, based on a plan to submit an NDA to the FDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by the applicant, and for which the applicant has not obtained a right of reference. As a result of our interactions with the FDA during 2008, our current clinical development plan for Acetavance includes two pivotal efficacy clinical trials, two pharmacokinetic trials, and two safety trials, as well as other supportive studies conducted by Cadence or BMS, or reported in scientific and medical literature. We have completed all of these studies. The data that we plan to submit in support of our NDA for Acetavance from our own clinical trials, and from clinical trials conducted by BMS and others, must be collected, reviewed for quality, and analyzed, and must provide evidence of adequate safety and efficacy in order for the FDA to approve our NDA. Assuming the successful completion of our ongoing manufacturing development activities for Acetavance, we currently plan to submit an NDA to the FDA in the second quarter of 2009, requesting marketing approval of Acetavance for the treatment of acute pain and fever in adults and children. 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, omiganan pentahydrochloride 1% aqueous gel, or Omigard, and subsequently reached an agreement under the special protocol assessment, or SPA, process with the FDA concerning the protocol for a single, Phase III clinical trial for Omigard. The SPA process provides a product sponsor with an agreement from the FDA that the design and analysis of the trial are adequate to support the submission of an NDA if the trial is performed according to the SPA; however, such agreements with the FDA remain subject to advances in the field or public health concerns unrecognized at the time of the FDA's protocol assessment. In April 2008, we completed enrollment in our Phase III clinical trial of Omigard for the prevention of local catheter site infections, or LCSIs. The data from this trial must be collected, reviewed for quality and analyzed, and must demonstrate a positive result before we can submit an NDA to the FDA for the approval of Omigard. The protocol for the CLIRS trial requires that blinded data from patients treated in the study be reviewed by independent experts to determine the presence or absence of catheter-related infections. In recognition of the complexity of the patient data and the importance of a robust outcome assessment, we initiated discussions with the FDA in 2008, proposing a review of the blinded data by an additional group of independent experts, using the same protocol definitions and adjudication criteria as were provided to the initial group. The FDA agreed with our proposal, and we expect that the blinded data assessments will be completed in the first quarter of 2009. Our discussions with the FDA regarding the statistical analysis plan remain ongoing and must be completed before we unblind and analyze the data from this trial. We expect to announce the topline results of this clinical trial in the first quarter of 2009, and, assuming that the results are positive, to submit an NDA for Omigard to the FDA in the second quarter of 2009, however, any additional delays in completing these activities could delay the submission and review by the FDA of any NDA for this product candidate.

Our 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 regulatory agencies outside the U.S. We may also fail to obtain the necessary approvals if we have inadequate financial or other resources to complete our clinical and manufacturing development programs and prepare to submit applications for marketing approval of our product candidates. Any failure to obtain approval of Acetavance or Omigard would have a material and adverse effect 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 provide adequate data from 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, 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 clinical 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, which is called the CLIRS trial, in August 2005. In July 2007, we increased the number of patients to be enrolled in the CLIRS trial from 1,250 to 1,850 patients in order to increase the statistical power of the study. This change was prompted by our planned re-analysis of data from the initial Phase III clinical trial of Omigard, which 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%. Increasing the number of patients enrolled in this clinical trial required greater financial resources than originally anticipated and delayed the completion of enrollment.

The protocol for the CLIRS trial requires that blinded data from patients treated in the study be reviewed by independent experts to determine the presence or absence of catheter-related infections. In recognition of the complexity of the patient data and the importance of a robust outcome assessment, we initiated discussions with the FDA in 2008 proposing a review of the blinded data by an additional group of independent experts, using the same protocol definitions and adjudication criteria as were provided to the initial group. The FDA agreed with our proposal, and we expect that the blinded data assessments will be completed in the first quarter of 2009. Our discussions with the FDA regarding the statistical analysis plan remain ongoing and must be completed before we unblind and analyze the data from this trial. We expect to announce the topline results of this clinical trial in the first quarter of 2009 and, assuming that the results are positive, to submit an NDA for Omigard to the FDA in the second quarter of 2009.

Although the FDA agreed with our proposals to increase the number of patients enrolled in the CLIRS trial and to add a second independent expert assessment of the data, we may still be unable to demonstrate statistical significance or otherwise demonstrate sufficient efficacy and safety to support the filing of an NDA or ultimately lead to regulatory approval of Omigard. Furthermore, we cannot be certain how the FDA will analyze the results of the trial, particularly if the data assessments by the two independent expert groups for the trial differ, as the FDA often conducts its own analyses of data provided by sponsors. In addition, despite having completed the SPA process, the FDA's agreement with us on the trial protocol and data analysis plans remains subject to advances in the field or public health concerns unrecognized at the time of the FDA's protocol assessment.

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.

In December 2008, we announced that our Acetavance Phase III efficacy trial in patients who have undergone abdominal laparoscopic surgery met its primary endpoint of a statistically significant reduction in summed pain intensity differences from baseline over 24 hours compared to placebo. At the same time, we also announced that a recently completed safety study demonstrated that adult patients who received repeated doses of Acetavance had a hepatic and general safety profile comparable to patients in the control (non-Acetavance) arm of the study, and that a pharmacokinetic study of Acetavance in pediatric patients

demonstrated a pharmacokinetic profile that is generally comparable to adults, with an age-related reduction in clearance in newborns. The results of these studies will be included in our NDA submission for Acetavance. If the FDA does not agree with our interpretation of the results of these and other studies, our ability to obtain regulatory approval of this product candidate may be delayed, limited or otherwise adversely impacted.

The rejection of data from any of the clinical trials required by regulatory authorities to support NDAs for our product candidates 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. Nine post-operative pain clinical trials have been completed by BMS, mostly in Europe, primarily in support of European regulatory approvals for this product candidate. Although the FDA has advised us that one of these studies, a clinical trial in patients undergoing total hip and knee replacement, may be submitted to demonstrate efficacy of Acetavance in the treatment of post-operative pain, the FDA may reject the results of this study if it determines that the study was 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 for this study. Even though BMS has obtained marketing approval in Europe and other territories for intravenous acetaminophen, we must provide the FDA with 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 of 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. As a result, during the first quarter of 2008, we initiated communications with the FDA in order to obtain the agency's advice regarding our clinical development plan for this product candidate. In July 2008, we announced that we received written guidance from the FDA, confirming that our clinical development plan is sufficient to provide a basis for submission of a 505(b)(2) NDA for Acetavance. The Acetavance clinical development plan includes two pivotal efficacy clinical trials, two pharmacokinetic trials and two safety trials, as well as other supportive studies conducted by Cadence or BMS, or reported in scientific and medical literature. We have completed all of these studies. The data we submit to support our NDA for Acetavance from our own clinical trials and from clinical trials conducted by BMS and others must be collected, reviewed for quality, and analyzed before we can submit an NDA to the FDA requesting marketing approval of Acetavance, and the data must provide evidence of adequate safety and efficacy in order to obtain regulatory approval of this product candidate. Any delays in completing the collection, review or analysis of the data from this trial will delay the submission of an NDA with the FDA to obtain regulatory approval for this product candidate. If the results of any of the clinical trials submitted in support of our NDA are unfavorable or raise any concerns regarding the safety or efficacy of Acetavance, we may be forced to conduct additional pre-clinical studies or clinical trials, which would result in additional significant expense and delay. 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.

The data collected from our clinical trials or clinical trials conducted by our licensors 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 our standard procedures for summarizing, integrating and performing additional analyses 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. Our failure to successfully complete our clinical trials and obtain regulatory approval for Acetavance and Omigard would adversely affect our business and our stock price.

Our Omigard product candidate is not yet approved in any jurisdiction, and no antimicrobial peptide has been approved by the FDA. Two antimicrobial peptides with mechanisms of action similar to Omigard were studied in Phase III clinical trials, but these trials did not successfully achieve their primary objectives. Although Omigard was previously studied in more than 750 patients, all of the patients studied were enrolled in trials conducted or sponsored by Migenix or Fujisawa. 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 NDA or other applications for marketing authorization, we re-analyzed the data using a slightly different, stricter definition of LCSIs. 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, called the CLIRS trial, 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 increased the number of patients to be enrolled in the CLIRS trial from 1,250 to 1,850 patients. Increasing the number of patients in this study required greater financial resources than originally anticipated and delayed the completion of enrollment. 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 the CLIRS 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 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.

Recent publicity concerning the safety of certain drug products has resulted in heightened scrutiny by the FDA in the process of approving new drugs, which could delay or limit any regulatory approvals we may obtain for our product candidates.

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products after approval. In addition, the Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government's clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to conduct additional preclinical studies or clinical trials prior to approving our product candidates, we would face delays in our ability to obtain such approvals. If the FDA requires us to provide additional clinical or preclinical data following the approval of our product candidates, the indications for which our product candidates are approved may be limited, and our efforts to commercialize our product candidates may be otherwise adversely impacted.

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 are developing Acetavance for the treatment of acute pain and fever in adults and children, which will compete with well-established products for this and similar indications. Competing products available for the treatment of pain include 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. Ketorolac, an injectable non-steroidal

anti-inflammatory drug, or NSAID, is also available generically in the U.S. from several manufacturers. Competing products available for the treatment of fever in the hospital setting include acetaminophen administered orally and rectally, aspirin and NSAIDs, which may be administered orally, topically or intravenously. 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 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. Additionally, a chlorhexidine-containing, transparent dressing for the prevention of catheter-related infections has also been recently introduced into the U.S. market by 3M Corporation, and other competitive products may also be under development.

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.

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 be more successful than us in manufacturing and marketing their products. We 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 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 adversely impact our ability to demonstrate a statistically significant treatment difference for Omigard 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. Delays in the completion of data analysis for our Phase III clinical trial of Omigard or any 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 Omigard for use in combination with chlorhexidine antisepsis for the prevention of LCSIs. Additionally, improvements in hospital infection control practices since we commenced enrollment in our Phase III clinical trial of Omigard are reported to have reduced catheter-related infection rates, which may result in the occurrence of an insufficient number of infections to demonstrate a statistically significant treatment difference in this clinical trial. 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.

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 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.

If concerns are raised regarding the safety of a new drug as a result of undesirable side effects identified during clinical testing, the FDA may decline to approve the drug at the end of the normal NDA review period and issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the drug. The number of such requests for additional data or information issued by FDA in recent years has increased, and resulted in substantial delays in the approval of several new drugs. Undesirable side effects caused by our product candidates could interrupt, delay or halt clinical trials, and could result in the issuance of a request for additional data or information in response to our NDA applications, 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 as a result of sales of the same formulation of intravenous acetaminophen by BMS in Europe and other countries, 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. Although 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 that we may conduct or thereafter. Additionally, the same active compound contained in Omigard is currently being developed for the treatment of dermatological diseases and disorders by Cutanea Life Sciences, Inc., or Cutanea, another licensee of Migenix. If Cutanea identifies new side effects or other adverse events related to the compound during its pre-clinical or clinical development activities, regulatory authorities may require us to perform additional non-clinical or clinical testing in order to address such concerns. Such additional testing would add costs and could delay or result in the denial of regulatory approval for Omigard.

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; or
- 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. It is also possible that other legislative proposals will be adopted, particularly in view of the recent 2008 presidential and congressional elections and the potential agenda of the new administration. 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. If the performance of these third parties is substandard, or if they fail to 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 depend on independent clinical investigators, medical institutions and contract laboratories to conduct our clinical trials for Acetavance and Omigard, and other third parties, such as CROs, expert data monitoring committees, and other consultants, to manage the execution of our clinical trials, which includes the collection, monitoring, analysis, evaluation and reporting of data. Although we rely on third parties to perform these tasks, we are responsible for oversight and for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. However, unforeseen delays in completion of the work by any of the third parties on whom we rely may impact the timing of release of results and subsequent NDA submission.

The FDA requires us and the third parties that manage the execution of clinical trials on our behalf to fully comply with the protocols for these studies, as well as with applicable regulations and standards, commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording, analyzing and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. CROs, investigators and other third parties are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If these third parties 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 our study protocols or with GCPs, our clinical trials may be compromised, the submission of FDA applications for product approval may be delayed, and we may not be able to obtain regulatory approval for our product candidates.

The third party contractors that execute our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Failure of these third parties to meet their obligations could adversely affect the clinical development of our product candidates. Moreover, these independent investigators, CROs and other third parties may also have relationships with other commercial entities, some of which may have competitive products under development or currently marketed. If these third parties 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, the data from our clinical trials may not be acceptable for inclusion in our regulatory submissions, and we may not be able to obtain regulatory approval for Acetavance, Omigard or future product candidates.

If changes made in scaling-up the manufacturing processes for our product candidates result in a lack of comparability between our commercial products and the materials used in our clinical trials, we may be required to perform additional non-clinical or clinical studies, which would increase our costs, delay the submission of our applications for regulatory approvals for our product candidates, result in the loss of potential revenues, and adversely affect our business.

We do not manufacture any of our product candidates, and we do not currently plan to develop any capacity to do so. We rely on third party manufacturers to manufacture and perform important pre-commercialization manufacturing development activities for our product candidates.

Our manufacturers will need to demonstrate that the facilities, equipment and processes used to manufacture our products for potential commercial distribution are capable of consistently producing a product that meets all applicable quality criteria, and that is comparable to the product that was used in our clinical trials. For example, although clinical trials were conducted using product manufactured by BMS, if Acetavance is approved, we plan to purchase this product from Baxter Healthcare Corporation, or Baxter, for commercial distribution. Similarly, our clinical trials for Omigard were conducted using product for which the active pharmaceutical ingredient, or API, was manufactured by one contract manufacturer, while we may purchase the API to manufacture this product for commercial distribution from another manufacturer, Solvay, S.A, or Solvay.

If the FDA determines that any of the changes in manufacturers, facilities, equipment, processes or materials that are made in scaling-up the manufacturing processes for our product candidates resulted in a lack of comparability between the product used in our clinical trials and the product manufactured for commercial distribution, we may be required to complete additional non-clinical studies or clinical trials in order to obtain regulatory approvals for our product candidates, which would increase our costs, result in the loss of potential revenues and adversely affect our business.

If our contract manufacturers fail to complete pre-commercialization manufacturing development activities for our product candidates on a timely basis, including the completion of batches of our product candidates that are required to perform stability studies, or if our manufacturers fail to comply with stringent regulatory requirements, we will face delays in our ability to obtain regulatory approval for, and to commercialize, our product candidates, and our costs will increase.

Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems may include unanticipated failures of production equipment, limited availability of critical materials, equipment and facilities, inadequate yields, shortages of qualified personnel, and quality control difficulties. In order to receive regulatory approval to commercialize our product candidates, we will need to provide the FDA with comprehensive information regarding the validation of the manufacturing facilities, equipment and processes of our third party manufacturers. Additionally, our manufacturers must produce specific batches of our product candidates that demonstrate acceptable stability under various conditions and for commercially viable lengths of time. The production of these batches requires complex, highly specialized equipment and materials, and involves the development of new processes and methods that may take a substantial amount of time to implement. Any delays in the availability of stability data, whether due to scheduling issues, equipment or process failures, materials shortages, or other reasons, may cause delays in the submission of applications for regulatory approval of our product candidates, and consequent delays in receiving FDA or other regulatory authority approvals.

Additionally, the FDA conducts 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, the approval of our marketing applications may be delayed, existing product batches may be recalled or otherwise compromised, and we may experience delays in the availability of our product candidates for commercial distribution.

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

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. If the commercial manufacturers upon whom we rely to manufacture Acetavance and Omigard, and any other product candidates we may in-license, fail to deliver the required commercial quantities on a timely basis at commercially reasonable prices, 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 for the completion of pre-commercialization manufacturing development activities and the manufacture of commercial supplies of the finished Acetavance, and in December 2008 we entered into a supply and license agreement with Solvay for the commercial supply of the API for Omigard. Any termination or disruption of our relationships with Baxter or Solvay may materially harm our business and financial condition, and frustrate any commercialization efforts for this product candidate. The FDA and comparable international regulatory authorities must approve the facilities and processes of our contract manufacturers, which may 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 for commercial distribution.

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 the finished drug product for Omigard. If we need to change to other manufacturers or significantly change the manufacturing processes for our product candidates, we may be required to repeat or perform additional pre-clinical or clinical testing, which could increase our costs and cause delays in our ability to obtain regulatory approvals. Additionally, we may not be able to establish or maintain commercial manufacturing arrangements on commercially reasonable terms for any other product candidates that we may in-license or acquire. All manufacturers of our product candidates must comply with strictly enforced federal, state and foreign regulations, including 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 September 30, 2008, we had 49 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 development activities, prepare for the commercialization of our product candidates, if approved. 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 the activities associated with the collection, review and analysis of data from our clinical trial programs for Acetavance and Omigard;
- obtain and manage the substantial additional resources that are required to prepare and successfully file NDAs for both of our product candidates during the first half of 2009, including a significant number of consultants, CROs and other service providers;
- ensure that our consultants, CROs and other service providers successfully carry out their contractual obligations, provide high quality results, and meet expected deadlines;
- continue to carry out our own contractual obligations to our 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;
- 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. 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 only covers 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 or prevention in humans of burn-related or surgery-related infections, and the topical administration to a device or the site around the device for the treatment or prevention in humans of device-related infections, including local catheter site infections and catheter-related blood stream 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, or whether any financial difficulties experienced by our licensors could result in their unwillingness or inability to secure, maintain and enforce patents protecting our intellectual property.

We depend on our licensors, BMS, SCR Pharmatop, and Migenix, to protect the proprietary rights covering Acetavance and Omigard and 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 patent rights and prosecuting patent applications to our advantage.

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. 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. Regarding Omigard, Migenix is responsible for maintaining issued patents and prosecuting patent applications. 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.

Moreover, our licensors may experience serious difficulties related to their overall business or financial stability, and they may be unwilling or unable to continue to expend the financial resources required to maintain and prosecute these patents and patent applications. For example, in May 2008, Migenix announced that it was taking aggressive steps to reduce expenses and raise additional capital required to continue its key development activities and extend its cash position into 2009. In October 2008, Migenix announced that it was implementing additional cost-cutting measures, including a significant reduction in the number of its personnel and the consolidation of its operations at its head office in Vancouver, British Columbia, Canada. Any material adverse impact on Migenix's overall business or financial stability could result in its unwillingness or inability to secure, maintain and enforce patents protecting our intellectual property.

As part of a financing transaction, Migenix 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 the patents and patent applications covering Omigard, we cannot be sure that the lenders will have adequate expertise or resources to properly perform Migenix's 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 defend such challenge, 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 and trade secrets 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 either 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. According to the U.S. Patent and Trademark Office, a patent application corresponding to this European patent was also filed in the U.S. but has been abandoned. 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 Canadian patent application issues 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 in Canada, 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 Canadian application should it issue as a patent, the outcome of any litigation relating to this European patent and the Canadian patent application, 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 would not be 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.

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, including net losses of $51.7 million, $52.2 million and $7.7 million for the years ended December 31, 2007, 2006 and 2005, respectively. As of September 30, 2008, we had an accumulated deficit of $157.5 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 to decrease over the next few years due to the significant completion of our existing clinical development programs. However, our expenses to support regulatory approval and product manufacturing are expected to increase in connection with activities required to prepare and file NDAs for both of our product candidates during the first half of 2009. Further, we expect to incur increased pre-commercialization expenses during the second half of 2009 as we prepare for the market launch of 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 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 clinical development programs for Acetavance and Omigard, including the collection, review and analysis of data, in preparation for filing NDAs for both of these product candidates;
- obtain regulatory approvals for one or both of our current product candidates, or any other product candidates that we may in-license or acquire;
- manufacture commercial quantities of any approved product candidates at acceptable cost levels; and
- develop a commercial organization and the supporting infrastructure required to 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 collect, review and analyze clinical data from our clinical trials to support regulatory approval of marketing applications for our product candidates;
- continue our development activities;
- qualify and outsource the commercial-scale manufacturing of our products under cGMP; and
- commercialize our product candidates, if approved by regulatory authorities.

As of September 30, 2008, 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 and our registered direct offering in the first quarter of 2008, will be sufficient to meet our projected operating requirements for the next twelve months. 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 costs of our efforts to prepare for the submission of NDAs for Acetavance, Omigard and any other product candidates that we may in-license or acquire, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the cost and timing of completion of outsourced commercial manufacturing supplies 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;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish; and
- the success of the commercialization of our products.

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, modification 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 product liability or 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 and secured an additional $15.0 million loan from the same parties and GE Business Financial Services Inc. Our amended loan and security agreement contains 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 our amended 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 amended 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, or NASDAQ. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate 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. As a result, we are required to perform an evaluation of our internal controls over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes-Oxley Act. Additionally, our independent auditors are required to perform a similar evaluation and report on the effectiveness of our internal controls over financial reporting. These efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal controls over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

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 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 amended loan and security agreement with Silicon Valley Bank, Oxford Finance Corporation and GE Business Financial Services Inc. 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. In recent months, the volatility in the overall capital markets has reached unprecedented levels. Since our initial public offering in October 2006 through September 30, 2008, the trading prices for our common stock ranged from a high of $18.55 to a low of $4.84.

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 for Acetavance and our Phase III clinical trial of Omigard;
- the results of clinical trial programs for Acetavance and Omigard 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 or the economy as a whole;
- price and volume fluctuations in the overall stock market;
- 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 our 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, 2008, our executive officers and directors and their affiliates together controlled approximately 47% 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;
- 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 amended loan and security agreement with Silicon Valley Bank, Oxford Finance Corporation and GE Business Financial Services Inc. 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 biotechnology and 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.