INDEVUS PHARMACEUTICALS INC Form 424B3 March 13, 2007 <u>Table of Contents</u>

> Filed Pursuant to Rule 424(b)(3) Registration No. 333-140271

# A MERGER PROPOSAL YOUR VOTE IS IMPORTANT

To the Stockholders of Indevus Pharmaceuticals, Inc. and the Stockholders of Valera Pharmaceuticals, Inc.:

The boards of directors of Indevus Pharmaceuticals, Inc. and Valera Pharmaceuticals, Inc. have each unanimously approved a merger of the two companies, with Valera continuing as a wholly-owned subsidiary of Indevus. The companies believe that the merger will create a leading specialty pharmaceutical company focused on urology and endocrinology. Your vote is very important and we ask for your support in approving the merger and the issuance of Indevus common stock to Valera stockholders pursuant to the merger agreement.

If the merger is completed, Valera stockholders will have the right to receive Indevus common stock and contingent stock rights to receive additional shares of Indevus common stock. The number of shares of Indevus common stock that Valera stockholders will receive will be based on an exchange ratio determined prior to the Valera stockholders meeting. This exchange ratio will be determined by dividing \$7.75 by the volume weighted average of the closing prices of Indevus common stock, which we refer to as the Indevus Common Stock Value, as reported by The Nasdaq Global Market during the 25 trading days ending five trading days prior to the date of the Valera stockholders meeting. However, if the Indevus Common Stock Value is greater than \$8.05, then the exchange ratio will be fixed at 0.9626 of a share of Indevus common stock for each share of Valera common stock, and if the Indevus Common Stock Value is less than \$6.59, then the exchange ratio will be fixed at 1.1766 shares of Indevus common stock.

In addition, Valera stockholders will have the right to receive three contingent stock rights, which we refer to as CSRs, for each of their shares of Valera common stock. Each CSR relates to one of three Valera product candidates in development Supprelin-LA, the ureteral stent and VP003 (Octreotide implant). Upon achievement of the applicable milestones approval of the particular product by the U.S. Food and Drug Administration, or FDA, and, in the case of Supprelin-LA, Indevus possessing a specified amount of inventory of commercially saleable units the CSRs relating to Supprelin-LA, the ureteral stent and VP003 (Octreotide implant) will become convertible into \$1.00, \$1.00 and \$1.50, respectively, worth of Indevus common stock calculated using the average of the per share closing sale prices of Indevus common stock as reported by The Nasdaq Global Market for the ten trading days ending three trading days prior to achieving the applicable milestone or milestones. The aggregate number of shares of Indevus common stock that may be issued in the event one or more CSRs become convertible into Indevus common stock is limited and may not exceed the number of shares of Indevus common stock issued as part of the merger consideration upon completion of the merger. If the applicable milestone or milestones are not achieved within three years of completing the merger in the case of Supprelin-LA and within five years of completing the merger in the case of the ureteral stent and VP003 (Octreotide implant), the respective CSRs will expire and no additional shares of Indevus common stock will be issued in connection with those CSRs.

(Continued on next page)

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THE SECURITIES TO BE ISSUED IN CONNECTION WITH THE MERGER OR DETERMINED IF THIS JOINT PROXY STATEMENT/PROSPECTUS IS ACCURATE OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

This joint proxy statement/prospectus is dated March 12, 2007 and is first being mailed to

stockholders of Indevus and Valera on or about March 14, 2007.

We anticipate that upon completion of the merger, depending upon the exchange ratio, Valera's former stockholders will own between 21% and 25% of the then outstanding shares of Indevus common stock (not including any shares of Indevus common stock that may be issued upon cancellation of Valera options or conversion of CSRs). Indevus stockholders will continue to own their existing Indevus shares, which will not be affected by the merger. Indevus common stock is listed on The Nasdaq Global Market under the symbol IDEV, and Valera common stock is listed on The Nasdaq Global Market under the symbol VLRX.

Your vote is very important. The merger cannot be completed unless Valera stockholders adopt the merger agreement and Indevus stockholders approve the issuance of Indevus common stock and contingent stock rights pursuant to the merger agreement. Completion of the merger is also subject to other customary conditions.

In connection with the merger, Indevus entered into voting agreements with two Valera stockholders Sanders Morris Harris, Inc. (and affiliated entities) and Psilos Group Partners II-S, L.P. owning, in the aggregate, approximately 41.23% of the shares of Valera common stock. Pursuant to the voting agreements, these stockholders have agreed, subject to limited exceptions, to vote all their Valera shares in favor of adoption of the merger agreement.

We are each holding meetings of our stockholders to vote on the proposals necessary to complete the merger and, in the case of Indevus, to approve certain other matters unrelated to the merger. More information about these meetings, the merger and the other business to be considered by Indevus stockholders is contained in this joint proxy statement/prospectus. We encourage you to read this joint proxy statement/prospectus carefully and in its entirety, including the section entitled <u>Risk Factors</u> beginning on page 34, before voting.

Regardless of whether you plan to attend your respective company s meeting, please take the time to vote by telephone or via the Internet in accordance with the instructions on the enclosed proxy card or by completing and returning the proxy card in the enclosed envelope. If you are either a Valera or Indevus stockholder and you sign, date and mail your proxy card without indicating how you want to vote, your proxy will be counted as a vote FOR the proposals to be voted on. If you are a Valera stockholder and you do not return your proxy card, or, if your shares are held in street name by a broker, and you fail to instruct your broker how to vote your shares, your failure to vote or instruct your broker will have the same effect as if you voted against the adoption of the merger agreement.

Indevus board of directors unanimously recommends that Indevus stockholders vote FOR the proposal to approve the issuance of Indevus common stock and CSRs in the merger and FOR the other Indevus proposals described in this joint proxy statement/prospectus. Valera s board of directors unanimously recommends that Valera stockholders vote FOR the proposal to adopt the merger agreement.

We enthusiastically support this merger of our companies and join with our respective boards of directors in recommending that you vote in favor of the proposals described in this joint proxy statement/prospectus.

Very truly yours,

Glenn L. Cooper, M.D.,

Chief Executive Officer and Chairman

Indevus Pharmaceuticals, Inc.

James C. Gale Chairman of the Board Valera Pharmaceuticals, Inc. David S. Tierney, M.D.

President and Chief Executive Officer

Valera Pharmaceuticals, Inc.

# **Indevus Pharmaceuticals, Inc.**

33 Hayden Avenue

Lexington, MA 02421-7966

(781) 861-8444

# NOTICE OF ANNUAL AND SPECIAL MEETING OF STOCKHOLDERS

An annual and special meeting of stockholders of Indevus Pharmaceuticals, Inc. will be held at The Conference Center at Waltham Woods, 860 Winter Street, Waltham, MA 02451 on Tuesday, April 17, 2007 at 11:00 a.m., local time, to consider and vote on the proposals listed below and to transact such other business that may properly come before the annual and special meeting or any adjournment or postponement of the annual and special meeting:

1. To approve the issuance of Indevus common stock and the contingent stock rights in connection with the merger contemplated by the Agreement and Plan of Merger, dated as of December 11, 2006, by and among Indevus, Hayden Merger Sub, Inc. (which is a wholly-owned subsidiary of Indevus) and Valera Pharmaceuticals, Inc., a copy of which is included as *Annex A* to the joint proxy statement/prospectus accompanying this notice;

2. To elect eight members of Indevus board of directors to serve until the 2008 annual meeting of stockholders and until their successors are elected and qualified;

3. To approve an amendment to Indevus Restated Certificate of Incorporation to increase the number of authorized shares of Indevus common stock from 120 million to 200 million;

4. To approve an amendment to Indevus 2004 Equity Incentive Plan to increase the number of shares of Indevus common stock reserved for issuance under the plan from 6,000,000 to 9,000,000;

5. To approve an amendment to Indevus 2004 Equity Incentive Plan to remove the 20% limitation on the number of certain types of awards that can be made with respect to the additional 3,000,000 shares proposed to be added to the plan as set forth above;

6. To approve an amendment to Indevus 1995 Stock Purchase Plan to increase the number of shares of Indevus common stock available for purchase under the plan from 800,000 to 1,050,000; and

7. To ratify the appointment of PricewaterhouseCoopers LLP as Indevus independent registered public accounting firm.

The close of business on March 12, 2007 has been fixed as the record date for determining those Indevus stockholders entitled to vote at the annual and special meeting. Accordingly, only stockholders of record at the close of business on that date will receive this notice of, and be eligible to vote at, the Indevus annual and special meeting or any adjournments or postponements of the Indevus annual and special meeting. Each of the items of business listed above is more fully described in the joint proxy statement/prospectus that accompanies this notice.

If Indevus stockholders wish to approve the merger, they must approve Proposal No. 1 relating to the issuance of Indevus common stock and contingent stock rights pursuant to the Agreement and Plan of Merger. The proposals to amend the Indevus Restated Certificate of Incorporation, the equity incentive plan and the stock purchase plan and to ratify the appointment of PricewaterhouseCoopers LLP as Indevus independent registered public accounting firm are not conditions to completion of the merger.

The proposals require different percentages of votes in order to approve them:

The issuance of Indevus common stock and contingent stock rights pursuant to the merger agreement, the amendments to Indevus 2004 Equity Incentive Plan, the amendment to Indevus 1995 Employee Stock Purchase Plan and the ratification of PricewaterhouseCoopers LLP as Indevus independent registered public accounting firm, require approval by the affirmative vote of a majority of the total number of votes cast on the particular proposal (with the Indevus common stock and preferred stock voting together as a single class);

The election of eight directors to Indevus board of directors requires the affirmative vote of a plurality of votes cast by the holders of Indevus common stock (with preferred stock not entitled to vote on this matter); and

Approval of the amendment to Indevus Restated Certificate of Incorporation requires the affirmative vote of both (i) a majority of the total number of votes of Indevus common stock and preferred stock outstanding and entitled to vote, voting together as a single class (regardless of whether such holders are present in person or represented by proxy at the annual and special meeting) and (ii) a majority of the outstanding shares of Indevus common stock, voting separately as a class.

**Your vote is very important.** Please read the joint proxy statement/prospectus and the instructions on the enclosed proxy card and then, whether or not you expect to attend the annual and special meeting in person, and no matter how many shares you own, please vote your shares as promptly as possible by telephone or via the Internet in accordance with the instructions on the enclosed proxy card, or by signing, dating and mailing the enclosed proxy card in the self-addressed, postage-paid envelope provided. Submitting a proxy now will help assure a quorum and avoid added proxy solicitation costs. It will not prevent you from voting in person at the annual and special meeting. You may revoke your proxy at any time before the vote is taken by following the procedures set forth in the section entitled The Indevus Annual and Special Meeting How to Change Your Vote beginning on page 73 of the joint proxy statement/prospectus that accompanies this notice.

The Indevus board of directors unanimously recommends that you vote FOR the issuance of Indevus common stock and contingent stock rights pursuant to the Agreement and Plan of Merger, FOR the election of the director nominees and FOR the approval of the other proposals listed above and described in the joint proxy statement/prospectus.

By Order of the Board of Directors,

Glenn L. Cooper, M.D. Chief Executive Officer and Chairman

Lexington, Massachusetts

March 12, 2007

Valera Pharmaceuticals, Inc.

7 Clarke Drive

Cranbury, NJ 08512

(609) 235-3000

# NOTICE OF SPECIAL MEETING OF STOCKHOLDERS

A special meeting of stockholders of Valera Pharmaceuticals, Inc. will be held at Valera s offices at 7 Clarke Drive, Cranbury, NJ 08512 on April 17, 2007, at 10:00 a.m., local time, to consider and vote on the proposal listed below and to transact such other business that may properly come before the special meeting or any adjournment or postponement of the special meeting:

1. To adopt the Agreement and Plan of Merger, dated as of December 11, 2006, by and among Indevus Pharmaceuticals, Inc., Hayden Merger Sub, Inc. (which is a wholly-owned subsidiary of Indevus) and Valera, a copy of which is included as *Annex A* to the joint proxy statement/prospectus accompanying this notice.

The close of business on March 12, 2007 has been fixed as the record date for determining those Valera stockholders entitled to vote at the special meeting. Accordingly, only stockholders of record at the close of business on that date will receive this notice of, and be eligible to vote at, the Valera special meeting or any adjournments or postponements of the Valera special meeting. The merger and the Agreement and Plan of Merger are more fully described in the joint proxy statement/prospectus that accompanies this notice.

Adoption of the Agreement and Plan of Merger requires the affirmative vote of Valera stockholders representing a majority of the outstanding shares of Valera common stock entitled to vote at the special meeting. Pursuant to voting agreements entered into with Indevus, two Valera stockholders owning, in the aggregate, approximately 41.23% of the outstanding shares of Valera common stock have agreed, subject to limited exceptions, to vote all of their shares in favor of the adoption of the Agreement and Plan of Merger.

Under applicable provisions of Delaware law, Valera stockholders have the right to dissent from the merger and obtain payment in cash of the fair value of their shares of Valera common stock, as determined by the Delaware Chancery Court. In order to perfect these appraisal rights, stockholders must give written demand for appraisal of their shares before the taking of the vote on the merger at the special meeting and must not vote in favor of adoption of the Agreement and Plan of Merger. A copy of the applicable Delaware statutory provision is included as *Annex H* to the joint proxy statement/prospectus accompanying this notice and a summary of this provision can be found in the section entitled Appraisal Rights for Valera Stockholders beginning on page 108 of the joint proxy statement/prospectus.

**Your vote is very important.** Please read the joint proxy statement/prospectus and the instructions on the enclosed proxy card and then, whether or not you expect to attend the special meeting in person, and no matter how many shares you own, please vote your shares as promptly as possible by telephone or via the Internet in accordance with the instructions on the enclosed proxy card, or by signing, dating and mailing the enclosed proxy card in the self-addressed, postage-paid envelope provided. Submitting a proxy now will help assure a quorum and avoid added proxy solicitation costs. It will not prevent you from voting in person at the special meeting. You may revoke your proxy at any time before the vote is taken by following the procedures set forth in the section entitled The Valera Special Meeting How to Change Your Vote beginning on page 77 of the joint

proxy statement/prospectus that accompanies this notice. You should not send any certificates representing Valera common stock with your proxy card.

Valera s board of directors unanimously recommends that you vote FOR the adoption of the merger agreement.

By Order of the Board of Directors,

James C. Gale Chairman of the Board

Cranbury, New Jersey

March 12, 2007

#### ADDITIONAL INFORMATION

This joint proxy statement/prospectus incorporates important business and financial information about Indevus from other documents that it has filed with the SEC and that have not been included in or delivered with this joint proxy statement/prospectus. This information is available to you without charge upon your request. You can obtain the documents incorporated by reference in this joint proxy statement/prospectus by requesting them in writing or by telephone from Indevus at:

Indevus Pharmaceuticals, Inc.

33 Hayden Avenue

Lexington, MA 02421-7966

(781) 861-8444

Attn: Investor Relations

Please note that copies of the documents provided to you will not include exhibits, unless the exhibits are specifically incorporated by reference in the documents or this joint proxy statement/prospectus.

# Please see the section entitled Where You Can Find More Information beginning on page 257 for a more detailed description of the information incorporated by reference into this joint proxy statement/prospectus.

Some of the information incorporated in this joint proxy statement/prospectus is also available to investors on Indevus website at *www.indevus.com*. None of the information included on Indevus website is incorporated by reference in this joint proxy statement/prospectus.

If you would like to request documents, Indevus must receive your request no later than April 10, 2007, in order for you to receive timely delivery of the documents in advance of the stockholders meeting. Documents will be distributed within one business day of receipt of such request.

In addition, Indevus stockholders that have questions about the Indevus annual and special meeting, the merger agreement or the proposed merger may contact:

The Altman Group

1200 Wall Street West

Lyndhurst, NJ 07071

#### 800-926-4985

#### www.altmangroup.com

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# QUESTIONS AND ANSWERS ABOUT THE MEETINGS AND THE MERGER

The following are some of the questions that you may have as a stockholder of Valera or as a stockholder of Indevus, and answers to those questions. These questions and answers are not meant to be a substitute for the information contained in the remainder of this document, and this information is qualified in its entirety by the more detailed descriptions and explanations contained elsewhere in this document. We urge you to read this document and the additional documents incorporated by reference into this joint proxy statement/prospectus carefully and in their entirety prior to making any decision relating to the proposals at the stockholders meetings.

# THE MERGER

# Q1: Why am I receiving this joint proxy statement/prospectus?

A1: Indevus and Valera have agreed to the acquisition of Valera by Indevus under the terms of a merger agreement that is described in this joint proxy statement/prospectus. A copy of the merger agreement is included as *Annex A* to this joint proxy statement/prospectus. We are delivering this document to you because it serves as both a joint proxy statement of Indevus and Valera and a prospectus of Indevus. It is a joint proxy statement because it is being used by our boards of directors to solicit the proxies of Indevus stockholders and Valera stockholders. It is a prospectus because Indevus is offering Indevus common stock and contingent stock rights in exchange for Valera common stock if the merger is completed.

In order to complete the merger, among other things, Indevus stockholders must vote to approve the issuance of Indevus common stock and contingent stock rights in the merger and Valera stockholders must vote to adopt the merger agreement. Indevus and Valera will hold separate meetings to obtain these approvals and, in the case of Indevus, to approve certain other matters unrelated to the merger.

This joint proxy statement/prospectus, which you should read carefully, contains important information about the merger, the merger agreement and the meetings of stockholders of Indevus and Valera.

# Q2: Why are the companies proposing the merger?

A2: Indevus and Valera both believe that a combination of the two companies will provide strategic and financial benefits by creating a leading specialty pharmaceutical company focused on urology and endocrinology with strengthened prospects for continued growth over the long-term. In addition, Valera also is proposing the merger to offer Valera stockholders the opportunity to participate in the growth and prospects of the combined company by receiving Indevus common stock and contingent stock rights in the merger. For a more complete description of the reasons for the merger, see the sections entitled The Merger Indevus Reasons for the Merger beginning on page 82 and The Merger Valera s Reasons for the Merger beginning on page 84.

# Q3: Do the boards of directors of Indevus and Valera recommend approval of the merger proposals?

A3: Yes. The boards of directors of both companies have unanimously approved the merger and unanimously recommend approval of the applicable merger proposals by the stockholders of their respective companies. For a more complete description of the recommendations of the respective boards of directors, see the sections entitled The Merger Indevus Reasons for the Merger beginning on page 82 and The Merger Valera s Reasons for the Merger beginning on page 84.

# Q4: Are there risks involved in undertaking the merger?

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Yes. In evaluating the merger, Indevus and Valera stockholders should carefully consider the factors disclosed in the section of this joint proxy statement/prospectus entitled Risk Factors beginning on

page 34, and other information included in this joint proxy statement/prospectus and the documents incorporated by reference in this joint proxy statement/prospectus.

### Q5: What will happen in the proposed merger?

A5: In the proposed merger, a wholly-owned subsidiary of Indevus will merge with and into Valera. After the merger, Valera will be a wholly-owned subsidiary of Indevus and will no longer be a public company. See the sections entitled The Merger Agreement The Merger beginning on page 112 and The Merger Agreement Closing and Effectiveness of the Merger beginning on page 113.

#### Q6: What will Valera stockholders receive if the merger occurs?

A6: In the proposed merger, Valera stockholders will have the right to receive Indevus common stock and three contingent stock rights to receive additional shares of Indevus common stock.

Valera stockholders will receive shares of Indevus common stock for their shares of Valera common stock based on an exchange ratio to be determined prior to the Valera stockholders meeting. This exchange ratio will be determined by dividing \$7.75 by the volume weighted average of the closing prices of Indevus common stock, which we refer to as the Indevus Common Stock Value, as reported by The Nasdaq Global Market during the 25 trading days ending five trading days prior to the date of the Valera stockholders meeting. However, if the Indevus Common Stock Value is greater than \$8.05, then the exchange ratio will be fixed at 0.9626 of a share of Indevus common stock for each share of Valera common stock, and if the Indevus Common Stock Value is less than \$6.59, then the exchange ratio will be fixed at 1.1766 shares of Indevus common stock for each share of Valera common stock. Cash will be paid to Valera stockholders in lieu of any fractional shares of Indevus common stock a Valera stockholder would otherwise be entitled to receive.

In addition, Valera stockholders will receive three contingent stock rights, which we refer to as CSRs, for each of their shares of Valera common stock. Each CSR relates to one of three Valera product candidates in development Supprelin-LA, the ureteral stent and VP003 (Octreotide implant). Upon achievement of the applicable milestones approval of the particular product by the U.S. Food and Drug Administration, or FDA, and, in the case of Supprelin-LA, Indevus possessing a specified amount of inventory of commercially saleable units the CSRs relating to Supprelin-LA, the ureteral stent and VP003 (Octreotide implant) will become convertible into \$1.00, \$1.00 and \$1.50, respectively, worth of Indevus common stock calculated using the average of the per share closing sale prices of Indevus common stock as reported by The Nasdaq Global Market for the ten trading days ending three trading days prior to achieving the applicable milestones. The aggregate number of shares of Indevus common stock that may be issued in the event one or more CSRs become convertible into Indevus common stock is limited and may not exceed the number of shares of Indevus common stock issued as part of the merger consideration upon completion of the merger. If the applicable milestone or milestones are not achieved within three years of completing the merger in the case of Supprelin-LA and within five years of completing the merger in the case of the ureteral stent and VP003 (Octreotide implant), the respective CSRs will expire and no additional shares of Indevus common stock will be issued in connection with those CSRs.

See the section entitled The Merger Agreement Merger Consideration beginning on page 113.

# Q7: What will Indevus stockholders receive if the merger occurs?

A7: Indevus stockholders will continue to own their existing Indevus shares. However, those shares will represent a smaller proportion of the outstanding shares of the combined company due to the issuance of Indevus common stock to Valera stockholders in connection with the merger. As a result of the merger, depending upon the exchange ratio, we estimate that current Indevus stockholders will own between approximately 75% and 79% of Indevus common stock following the merger (which does not account for any shares of Indevus common stock that may be issued upon cancellation of Valera options or conversion of the CSRs).

#### Q8: What will Valera option holders and Indevus option holders receive if the merger occurs?

A8: Valera option holders:

Upon the closing of the merger, each outstanding option to purchase shares of Valera common stock will be cancelled in exchange for the right to receive shares of Indevus common stock, the amount and timing of which will vary depending on whether holders of options to purchase shares of Valera common stock consent to the proposed treatment of such options. For a more detailed discussion of Valera stock options, please see the section entitled The Merger Agreement Treatment of Valera Options beginning on page 114.

Indevus option holders:

Each option to purchase shares of Indevus common stock outstanding upon the closing of the merger will remain outstanding following the closing of the merger and will be exercisable following the closing of the merger on the same terms as were applicable immediately prior to the merger.

#### Q9: How was the merger consideration determined?

**A9:** The merger consideration was determined in negotiations by the two companies and reflects the relative market prices of each company s common stock during the period preceding entering into the merger agreement and other factors that the boards of directors of each company considered relevant.

#### Q10: What vote is required to approve the merger?

A10: *Valera*: Valera stockholders must adopt the merger agreement by the affirmative vote of Valera stockholders representing a majority of the outstanding shares of Valera common stock entitled to vote at the special meeting. Pursuant to voting agreements entered into with Indevus, two Valera stockholders owning, in the aggregate, approximately 41.23% of the outstanding shares of Valera common stock have agreed, subject to limited exceptions, to vote their shares in favor of adoption of the merger agreement.

Because the affirmative vote required to adopt the merger agreement is based upon the total number of outstanding shares of Valera common stock, the failure to submit a proxy card (or to vote in person at the Valera special meeting) or the abstention from voting by a stockholder will have the same effect as a vote against adoption of the merger agreement. Brokers holding shares of Valera common stock as nominees will not have discretionary authority to vote those shares in the absence of specific voting instructions from the beneficial owners of those shares, so the failure to provide voting instructions to your broker, resulting in a broker non-vote, also will have the same effect as a vote against adoption of the merger agreement. See the section entitled The Valera Special Meeting Vote Required beginning on page 76.

*Indevus*: Indevus stockholders must approve the issuance of the Indevus common stock and CSRs pursuant to the merger agreement by the affirmative vote of the total number of votes cast on the proposal with Indevus common stock and preferred stock (voting on an as-if-converted basis) voting together as a single class. Abstentions and broker non-votes will have no effect on the outcome of the proposal. See the section entitled The Indevus Annual and Special Meeting Required Votes beginning on page 71.

#### Q11: When do you expect the merger to be completed?

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A11: If the stockholders of both Indevus and Valera approve their respective proposals related to the merger, we expect to complete the merger shortly after the stockholders meetings, subject to the satisfaction or waiver of the other conditions to the merger. However, neither Indevus nor Valera can assure you when or if the merger will occur.

# Q12: What are the material U.S. federal income tax consequences of the merger to Indevus stockholders and to Valera stockholders?

A12: Indevus and Valera intend for the merger to be treated as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended, which we refer to as the Code. If the

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merger qualifies as a reorganization, Valera stockholders generally will not recognize any gain or loss for U.S. federal income tax purposes upon the exchange of shares of Valera common stock for shares of Indevus common stock and the CSRs. Valera stockholders, however, will have to recognize gain or loss for federal income tax purposes in connection with cash received in lieu of fractional shares of Indevus common stock. In addition, a portion of any additional shares of Indevus common stock issued pursuant to the CSRs may be treated as taxable interest income to the Valera stockholders at the time such shares are issued. Indevus stockholders will not exchange their Indevus common stock in the merger and accordingly will not recognize any taxable gain or loss as a result of the merger. We strongly urge you to consult with a tax advisor to determine the particular U.S. federal, state, local or foreign income or other tax consequences of the merger to you. For more information, please see the section entitled The Merger Material United States Federal Income Tax Consequences beginning on page 104.

# Q13: Should I send in my stock certificates now?

A13: No. If you are a Valera stockholder and the merger is completed, Indevus will send you written instructions about how to exchange your stock certificates for shares of Indevus common stock and contingent stock rights. Please do not send in your stock certificates with your proxy. See the section entitled The Merger Agreement Exchange of Valera Stock Certificates; No Further Rights as Valera Stockholders beginning on page 115.

If you are an Indevus stockholder, you will not need to send in your stock certificates because your shares of Indevus common stock will remain outstanding after the merger.

#### Q14: Where will my shares of Indevus common stock be listed?

A14: After the merger, the shares of Indevus common stock will continue to be listed on The Nasdaq Global Market under the symbol IDEV. THE STOCKHOLDERS MEETINGS; VOTING YOUR SHARES

#### Q15: When and where are the stockholders meetings?

A15: The Indevus annual and special meeting of stockholders will be held at The Conference Center at Waltham Woods, 860 Winter Street, Waltham, MA 02451 on Tuesday, April 17, 2007 at 11:00 a.m., local time.

The Valera special meeting of stockholders will be held at Valera s offices at 7 Clarke Drive, Cranbury, NJ 08512 on Tuesday, April 17, 2007, at 10:00 a.m., local time.

For additional information relating to the Indevus and Valera meetings please see the section entitled The Indevus Annual and Special Meeting beginning on page 69 and the section entitled The Valera Special Meeting beginning on page 75.

# Q16: Who can vote at the meetings?

A16: Only holders of record of Indevus common stock and preferred stock as of the close of business on March 12, 2007, will be entitled to notice of and to vote at the Indevus annual and special meeting.

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Only holders of record of Valera common stock as of the close of business on March 12, 2007, will be entitled to notice of and to vote at the Valera special meeting.

- Q17: As an Indevus stockholder, why am I electing directors and being asked to consider the other Indevus proposals unrelated to the merger when Valera stockholders are only being asked to consider a proposal relating to the merger?
- A17: The timing of a special meeting to consider the merger would have occurred around the time Indevus would regularly hold its annual meeting. Indevus has determined to combine the two meetings in an effort

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to significantly reduce proxy statement printing and other meeting costs and administrative burdens on Indevus and to reduce the burden on Indevus stockholders who would otherwise receive two sets of proxy materials around the same time to consider and vote on two separate sets of stockholder voting matters. The election of Indevus directors, the proposals to amend the Indevus certificate of incorporation, equity incentive plan and stock purchase plan and the ratification of the appointment of PricewaterhouseCoopers LLP as Indevus independent registered public accounting firm are not conditions to the completion of the merger.

### Q18: If my shares are held in street name by my broker, will my broker automatically vote my shares for me?

**A18:** If your shares are held in the name of a bank or broker or other nominee, you will receive separate instructions from your bank, broker or other nominee describing how to vote your shares. The availability of telephonic or Internet voting will depend on the bank s or broker s voting process. Please check with your bank or broker and follow the voting procedures your bank or broker provides.

You should instruct your bank, broker or other nominee how to vote your shares. Although rules applicable to broker-dealers grant your broker discretionary authority to vote your shares without receiving your instructions on certain matters, your broker does not have discretionary authority to vote your shares for the adoption of the merger agreement, if you are a Valera stockholder, or for the issuance of Indevus common stock and CSRs pursuant to the merger agreement or the approval of the amendments to the equity incentive plan and the employee stock purchase plan, if you are an Indevus stockholder. If your broker does not receive voting instructions from you regarding those proposals, your shares will not be voted on those proposals.

#### Q19: What do I need to do now?

A19: After carefully reading and considering the information contained or incorporated by reference in this joint proxy statement/prospectus, please submit your proxy by telephone or via the Internet in accordance with the instructions set forth in the enclosed proxy card, or fill out, sign and date the proxy card, and then mail your signed proxy card in the enclosed prepaid envelope as soon as possible so that your shares will be represented at your company s stockholders meeting.

# Q20: Why is my vote important?

A20: If you do not submit your proxy by telephone or via the Internet, or if you do not return your card or instruct your broker how to vote any shares held for you in street name, Indevus and/or Valera might not have sufficient shares represented at their meeting to constitute a quorum that is required in order to take action on the proposals. In addition, because adoption of the merger agreement by Valera stockholders requires the approval of a majority of the Valera shares outstanding as of the record date, if you hold Valera shares and do not vote, the effect will be a vote against the merger.

# Q21: If I am going to attend my company s stockholders meeting, should I submit my proxy by telephone or via the Internet or return my proxy card or voting instruction card?

A21: Yes. Submitting your proxy by telephone or via the Internet or returning your signed and dated proxy card or voting instruction card ensures that your shares will be represented and voted at your respective company s stockholders meeting. Stockholders of record as of the record date for the respective meetings can vote in person at the meetings. If your shares are held in the name of a bank, broker or other nominee, then you are not a stockholder of record and you must ask your bank, broker or other nominee how you can vote at the stockholders meeting.

# Q22: Am I entitled to exercise any dissenters or appraisal rights in connection with the merger?

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A22: Valera stockholders: Yes.

Under Delaware law, Valera stockholders have the right to dissent from the merger and to receive payment in cash for the fair value of their shares of Valera common stock, as determined by the Delaware Chancery

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Court. In order to perfect appraisal rights, Valera stockholders must give written demand for appraisal of their shares before the taking of the vote on the merger at the special meeting and must not vote in favor of adoption of the merger agreement. **Merely voting against adoption of the merger agreement will not protect your rights to appraisal.** In order to protect your appraisal rights, you must adhere to all of the requirements set forth under Delaware law. A copy of the applicable Delaware statutory provision is included as *Annex H* to this joint proxy statement/prospectus and a summary of this provision can be found under the section entitled Appraisal Rights for Valera Stockholders beginning on page 108.

Indevus stockholders: No.

Indevus stockholders are not entitled to dissenters or appraisal rights under Delaware law in connection with the merger.

#### Q23: May I change my vote after I have submitted a proxy by telephone or via the Internet or mailed my signed proxy card?

A23: Yes. You can change your vote at any time before your proxy is voted at the respective stockholders meeting. If your shares are registered directly in your name, you can change your vote in any of the three following ways:

delivering to the Secretary of Indevus or Valera, as appropriate, a written notice, bearing a date later than the date of the proxy, stating that the proxy is revoked;

submitting a proxy at a later date by telephone or via the Internet, or by signing and delivering a proxy relating to the same shares and bearing a later date than the date of the previous proxy prior to the vote at the respective stockholders meeting, in which case your later-submitted proxy will be recorded and your earlier proxy revoked; or

attending the respective stockholders meeting and voting in person (your attendance at the meeting, in and of itself, will not revoke the proxy).

Alternatively, you may hand deliver a written revocation notice, or a later dated proxy, to the Secretary of the respective company at the meeting before voting begins.

If your shares are held by a bank, broker or other nominee, you must follow the instructions provided by the bank, broker or other nominee if you wish to change your vote. See the sections entitled The Indevus Annual and Special Meeting How to Change Your Vote beginning on page 73 and the section entitled The Valera Special Meeting How to Change Your Vote beginning on page 77. ADDITIONAL QUESTIONS

# Q24: Where can I find more information about Indevus and Valera?

- A24: You can find more information about Indevus and Valera from various sources described in the section entitled Where You Can Find More Information beginning on page 257.
- Q25: Who can help answer my questions?

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A25: If you are an Indevus stockholder and you have any questions about the merger or the other matters described in this joint proxy statement/prospectus or need assistance in voting your shares, or if you need additional copies of this joint proxy statement/prospectus or the enclosed proxy card, you should contact:

# The Altman Group

1200 Wall Street West

Lyndhurst, NJ 07071

800-926-4985

www.altmangroup.com

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Indevus stockholders and Valera stockholders that have questions may also contact their respective investor relations departments:

Indevus Pharmaceuticals, Inc.

33 Hayden Avenue

Lexington, MA 02421-7966

(781) 861-8444

Valera Pharmaceuticals, Inc.

7 Clarke Drive

Cranbury, NJ 08512

(609) 235-3000

Attn: Investor Relations

Attn: Investor Relations If your shares are held in the name of your broker or other nominee, you should also contact your broker or other nominee for additional information.

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#### SUMMARY

This summary highlights selected information contained elsewhere in this document and may not contain all the information that is important to you. Indevus and Valera urge you to read carefully the remainder of this document, including the attached annexes and the other documents to which we have referred you, for a more complete understanding of the merger and the other matters being considered at the applicable stockholders meeting. See the section entitled Where You Can Find More Information beginning on page 257. We have included page references to direct you to a more complete description of the topics presented in this summary.

#### THE COMPANIES

#### Indevus (Page 137)

#### Business

Indevus Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. Indevus currently markets two products through its approximately 80-person specialty sales force and it has six products in development. Indevus marketed products include SANCTUR<sup>®</sup> for overactive bladder, which it co-promotes with its partner Esprit Pharma, Inc., which we refer to in this joint proxy statement/prospectus as Esprit, and DELATESTRYL<sup>®</sup> (testosterone enanthate) for the treatment of male hypogonadism.

Indevus core urology and endocrinology portfolio contains four compounds in development in addition to its marketed products SANCTURA and DELATESTRYL. Its most advanced compound is SANCTURA XR, the once-daily formulation of SANCTURA. In October 2006, Indevus submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, seeking approval to market SANCTURA XR. NEBIDO<sup>®</sup>, for male hypogonadism, is currently in a fully-enrolled, Phase III pharmacokinetic study and Indevus expects to submit an NDA for NEBIDO in mid-2007. PRO 2000, a topical microbicide for the prevention of infection by HIV and other sexually-transmitted diseases, is in two ongoing Phase III trials. IP 751 is for pain and inflammatory disorders, including interstitial cystitis.

In addition to its core urology and endocrinology portfolio, Indevus is preparing to begin a Phase III development program for pagoclone, a GABA-A (gamma amino butyric acid) receptor modulator which it is developing for the treatment of persistent developmental stuttering. Indevus product portfolio also contains aminocandin, an echinocandin for systemic fungal infections for which Indevus recently licensed worldwide rights to Novexel S.A, a spin-out company from sanofi-aventis. Indevus also is receiving royalties under a patent it licensed to Eli Lilly & Company based on net sales of Sarafem<sup>®</sup> in the United States. Sarafem is prescribed to treat certain conditions and symptoms associated with pre-menstrual dysphoric disorder.

#### Strategy

Indevus goal is to become a leading specialty pharmaceutical company focused on urology and endocrinology. The key elements of the strategy that Indevus employs in its efforts to achieve its goal include:

(1) Identifying and acquiring products or product candidates that have differentiating features and defined specialty markets within Indevus core focus area.

(2) Adding value to acquired development stage compounds through research, pre-clinical development, clinical testing and regulatory activities.

(3) Commercializing products with our specialty sales force or in collaboration with corporate partners in order to help ensure broader penetration of target markets.

# Core Focus Area Urology and Endocrinology

In urology and endocrinology, Indevus believes it has developed strong capabilities in product development based on its research and development organization and in sales and marketing based on its approximately 80-person specialty sales force.

Through Indevus business development efforts and its research and development capabilities, Indevus has a robust late-stage product pipeline. Indevus believes its capabilities will enable it to continue to successfully acquire, develop and commercialize products and product candidates and achieve its strategic goal of becoming a leading specialty pharmaceutical company in its core focus area.

The following table outlines the products in Indevus core focus area:

Product Name	Indication/Use	Status	<b>Commercial Rights</b>
SANCTURA	Overactive bladder	Marketed	U.S. <sup>1</sup>
SANCTURA XR	Overactive bladder	NDA <sup>2</sup> filed	Worldwide <sup>3</sup>
DELATESTRYL	Hypogonadism	Marketed	U.S.
NEBIDO	Hypogonadism	Phase III	U.S.
PRO 2000	HIV and STD prevention	Phase III	Worldwide
IP 751	Interstitial cystitis/pain	Phase I	Worldwide

<sup>1</sup> Licensed to Esprit.

<sup>2</sup> NDA refers to a New Drug Application.

<sup>3</sup> Licensed to Esprit in the U.S.; certain territories outside the U.S. licensed to Madaus GmbH.

#### **Other Products**

In addition to the products and product candidates in Indevus core focus area, it has products and product candidates that address certain other specialty medical areas.

The following table summarizes the status of Indevus other products:

Product Name	Indication/Use	Status	<b>Commercial Rights</b>
Sarafem	Premenstrual Dysphoric Disorder	Marketed	Worldwide <sup>1</sup>
Pagoclone	Stuttering	Phase III	Worldwide
Aminocandin	Systemic fungal infections	Phase I	Worldwide <sup>2</sup>

<sup>1</sup> Licensed to Eli Lilly & Company

<sup>2</sup> Know-how licensed to Novexel S.A.

Indevus Pharmaceuticals, Inc. is a Delaware corporation. Its principal office is located at 33 Hayden Avenue, Lexington, Massachusetts 02421-7971, and its main telephone number is (781) 861-8444. Reports, proxy statements and other information concerning Indevus may be accessed and reviewed through its website: http://www.indevus.com.

Indevus registered trademark SANCTURA is assigned in the U.S. to Esprit Pharma Holding Company (subject to our co-exclusive right to use it) and NEBIDO is a registered trademark of Schering AG, Germany that Indevus exclusively licenses in the United States. DELATESTRYL is Indevus registered trademark for its

DELATESTRYL product. Indevus has pending trademark applications for SANCTURA XR. Other trademarks, trade names and service marks appearing in this registration statement are the property of their respective owners.

# Valera (Page 139)

### Overview

Valera Pharmaceuticals is a specialty pharmaceutical company concentrating on the development, acquisition and commercialization of products for the treatment of urological and endocrine conditions, diseases and disorders, including products that utilize Valera's proprietary drug delivery technology. Valera's first product, Vantas, was approved by the U.S. Food and Drug Administration, or FDA, in October 2004. Vantas is a 12-month implant indicated for the palliative treatment of advanced prostate cancer. Vantas slows prostate tumor growth by delivering histrelin, a luteinizing hormone-releasing hormone agonist, or LHRH agonist. Valera began marketing Vantas in November 2004 utilizing its sales force. In December 2006, Valera entered into a co-promotion agreement with Indevus and in January 2007, pursuant to the co-promotion arrangement, Valera and Indevus began to jointly promote Vantas with Indevus with an aggregate sales force of approximately 105 individuals that are currently calling on urologists in the United States that account for the majority of LHRH agonist product sales. In addition to Vantas, Valera is developing a pipeline of product candidates for indications that include central precocious puberty, acromegaly, bladder cancer, opioid addiction, interstitial cystitis, nocturnal enuresis and bladder cancer.

Total U.S sales of LHRH agonist products for the palliative treatment of prostate cancer were approximately \$850 million in 2006 based on Valera's estimates and IMS Health Incorporated data, with the leading products being three- and four-month injection formulations. Valera's believes that total U.S. sales of LHRH agonist products declined by approximately 5% in 2006, primarily as a result of lower prices due to changes in Medicare reimbursement rates. Valera believes that Vantas has a competitive advantage over other products because it delivers an even, controlled dose of LHRH agonist over a 12-month period, and is the only product indicated for the palliative treatment of advanced prostate cancer that delivers histrelin, the most potent LHRH agonist available on the market.

Vantas is a hydrogel implant based on Valera s patented Hydron Technology, which is a drug delivery system that allows Valera to control the amount and timing of the release of drugs into the body for up to 12 months. Several of Valera s product candidates utilize its Hydron Technology delivery system. The hydrogel implant is a soft and flexible implant containing no moving parts. Valera intends to leverage its specialized sales force to market certain of its product candidates, if approved, since the indications of these product candidates are treated by many of the same physicians Valera is calling on for Vantas.

#### Valera s Competitive Strengths

Valera believes that its key competitive strengths that allow it to compete effectively in the urology and endocrinology markets include:

*Technology*. Valera believes that Hydron Technology offers significant advantages over existing drug delivery systems. Implants using Hydron Technology can be adapted to deliver many kinds of drugs over an extended period of time. In addition, Valera s implants are soft and flexible, enhancing patient comfort. Further, because Valera owns the manufacturing know-how to develop products utilizing Hydron Technology, Valera is able to control and maximize the potential commercial uses of this technology.

*Development Capability.* As demonstrated by Vantas, Valera has succeeded in developing a product, successfully taking it through the regulatory process to market in the United States in less than a year

from the submission of a new drug application without utilizing an accelerated approval process. However, Valera may not be able to obtain FDA approval for its product candidates as quickly as it did for Vantas. Valera expects to continue to utilize this capability to efficiently develop future products.

*Manufacturing Ability*. Valera manufactures Vantas and Valera s product candidates utilizing Hydron Technology using a patented and proprietary process. In addition, Valera has developed proprietary equipment and scalable manufacturing methods to achieve cost-effective commercial production. Further, because Valera controls the manufacture of Vantas and Valera s product candidates that use Hydron Technology, Valera can ensure high quality and fully realize any manufacturing cost efficiencies.

*Sales and Marketing.* Valera and its co-marketing partner, Indevus, are currently calling on urologists that account for the majority of LHRH agonist product sales in the United States. By adjusting Valera s current sales force structure slightly, Valera will be able to call on physicians in additional specialty areas, such as pediatric endocrinology. These therapeutic areas are attractive because they can be effectively targeted with a small, focused sales force. Valera also believes that the direct physician distribution channel of Vantas may present a barrier to the future entry of competition from generic products because generic drug companies do not typically have field sales forces. Outside the United States, Valera has partnered with companies with a local presence and proven distribution channels in the urology market for distribution of Vantas.

# **Product Development**

The following table summarizes certain information regarding Vantas and Valera s product candidates:

Product	Indication	Therapeutic Area	<b>Delivery Method</b>	Status
Vantas	Prostate Cancer	Urology	Implant	United States Commercial Sales; Approved in Denmark and Canada
Supprelin <sup>®</sup> -LA	Central Precocious Puberty (early onset of puberty)	Endocrinology	Implant	New Drug Application Filed
VP003 (Octreotide)	Acromegaly (giantism)	Endocrinology	Implant	Phases I/II
VP004 (Naltrexone)	Addiction Disorders	Central Nervous System	Implant	Phase I/II
VP005 (Anti-inflammatory)	Interstitial Cystitis (bladder inflammation)	Urology	Bladder Instillation	Pre-clinical
VP006 (Peptide)	Nocturnal Enuresis (bed wetting)	Urology	Oral Tablet	Phase I
Valstar <sup>®</sup> (Valrubicin)	Bladder Cancer	Urology	Bladder Instillation	New Drug Application Approved
Endoureteral Stent	Maintenance of Ureteral Patency	Urology	Insertion	Pivotal Animal Study

Valera is a Delaware corporation. Its principal office is located at 7 Clarke Drive, Cranbury, NJ 08512, and its main telephone number is (609) 235-3000. Reports and other information concerning Valera may be accessed and reviewed through its website at *www.valerapharma.com*.

#### Hayden Merger Sub, Inc.

# Hayden Merger Sub, Inc.

33 Hayden Avenue

Lexington, Massachusetts 02421-7971

Telephone: (781) 861-8444

Hayden Merger Sub, Inc., which we refer to as Merger Sub, is a Delaware corporation and a direct wholly-owned subsidiary of Indevus, formed on December 7, 2006 for the sole purpose of effecting the merger. If the merger is completed, Hayden Merger Sub, Inc. will cease to exist following its merger with and into Valera.

#### THE MERGER

#### The Merger (Page 79)

The boards of directors of Indevus and Valera each unanimously approved the merger of Indevus and Valera on the terms and subject to the conditions of an Agreement and Plan of Merger, dated as of December 11, 2006, by and among Indevus, Merger Sub and Valera, which we refer to as the merger agreement. We have included the merger agreement as *Annex A* to this joint proxy statement/prospectus, and encourage you to read the entire merger agreement carefully because it is the legal document governing the merger.

Under the terms of the merger agreement, Merger Sub will merge with and into Valera and the separate corporate existence of Merger Sub will cease. Valera will be the surviving corporation in the merger and will continue as a wholly-owned subsidiary of Indevus. Stockholders of Indevus will continue to own their existing shares of Indevus common and preferred stock.

If the stockholders of both Indevus and Valera approve their respective proposals related to the merger, we expect to complete the merger shortly after the stockholders meetings, subject to the satisfaction or waiver of the other conditions to the merger. However, neither Indevus nor Valera can assure you when or if the merger will occur.

# What Valera Stockholders Will Receive in the Merger (Page 113)

In the proposed merger, Valera stockholders will have the right to receive Indevus common stock and three contingent stock rights to receive additional shares of Indevus common stock.

Valera stockholders will receive shares of Indevus common stock for their shares of Valera common stock based on an exchange ratio to be determined prior to the Valera stockholders meeting. This exchange ratio will be determined by dividing \$7.75 by the volume weighted average of the closing prices of Indevus common stock, which we refer to as the Indevus Common Stock Value, as reported by The Nasdaq Global Market during the 25 trading days ending five trading days prior to the date of the Valera stockholders meeting. However, if the Indevus Common Stock Value is greater than \$8.05, then the exchange ratio will be fixed at 0.9626 of a share of Indevus common stock for each share of Valera common stock, and if the Indevus Common Stock Value is less than \$6.59, then the exchange ratio will be fixed at 1.1766 shares of Indevus common stock for each share of Valera common stock. Cash will be paid to Valera stockholders in lieu of any fractional shares of Indevus common stock a Valera stockholder would otherwise be entitled to receive.

In addition, Valera stockholders will receive three contingent stock rights, which we refer to as CSRs, for each of their shares of Valera common stock. Each CSR relates to one of three Valera product candidates in development Supprelin-LA, the ureteral stent and VP003 (Octreotide implant). Upon achievement of the applicable milestones approval of the particular product by the U.S. Food and Drug Administration, or FDA, and, in the case of Supprelin-LA, Indevus possessing a specified amount of inventory of commercially saleable units the CSRs relating to Supprelin-LA, the ureteral stent and VP003 (Octreotide implant) will become convertible into \$1.00, \$1.00 and \$1.50, respectively, worth of Indevus common stock calculated using the average of the per share closing sale prices of Indevus common stock as reported by The Nasdaq Global Market for the ten trading days ending three trading days prior to achieving the applicable milestones. The aggregate number of shares of Indevus common stock that may be issued in the event one or more CSRs become convertible into Indevus common stock is limited and may not exceed the number of shares of Indevus common stock issued as part of the merger consideration upon completion of the merger. If the applicable milestone or milestones are not achieved within three years of completing the merger in the case of Supprelin-LA and within five years of completing the merger in the case of the ureteral stent and VP003 (Octreotide implant), the respective CSRs will expire and no additional shares of Indevus common stock will be issued in connection with those CSRs.

# What Holders of Valera Stock Options Will Receive in the Merger (Page 114)

Upon the closing of the merger, each outstanding option to purchase shares of Valera common stock will be cancelled in exchange for the right to receive the following consideration:

Option holders that consent to the proposed treatment of Valera options will receive the following with respect to each share of Valera common stock underlying the option:

Options with a per share exercise price below \$7.75 will receive, at closing, a number of shares of Indevus common stock equal to (x) the excess of \$7.75 over the per share exercise price of the option divided by (y) the Indevus Common Stock Value (but not less than \$6.59 nor more than \$8.05); and Indevus unfunded and unsecured promise to issue, in the future, the number of shares of Indevus common stock that would have been issuable had option holders received CSRs.

Options with a per share exercise price of \$7.75 or greater will receive Indevus unfunded and unsecured promise to issue, in the future, a number of shares of Indevus common stock determined by a formula intended to provide value equivalent to the CSRs, net of the option exercise price exceeding \$7.75.

Option holders that do not provide consent to the proposed treatment of Valera options will receive the following:

Options with a per share exercise price below the closing price of Valera common stock on the trading day immediately preceding the closing of the merger will receive shares of Indevus common stock based on the spread between Valera's closing stock price on the trading day immediately preceding the closing of the merger and the exercise price of the option, but will not receive CSRs.

Options with a per share exercise price equal to or greater than the closing price of Valera common stock on the trading day immediately preceding the closing of the merger will not be entitled to any consideration upon cancellation. Cash will be paid to Valera option holders in lieu of any fractional shares of Indevus common stock an option holder would otherwise be entitled to receive.

# **Ownership of Indevus after the Merger**

The percentage ownership of Indevus by former Valera stockholders upon completion of the merger will depend upon the determination of the exchange ratio. Based upon the number of shares of Indevus and Valera capital stock outstanding on January 1, 2007 (excluding shares issuable upon exercise of outstanding Indevus and Valera stock options) we estimate that former Valera stockholders will own between approximately 21% and 25% of the then outstanding shares of Indevus common stock after completion of the merger (not including any shares of Indevus common stock that may be issued upon cancellation of Valera options or conversion of CSRs). In particular, we estimate that certain affiliates of Valera will own between approximately 13% and 15% of the then outstanding shares of Indevus common stock that may be issued upon stock that may be issued upon cancellation of the merger (which does not account for any shares of Indevus common stock that may be issued upon cancellation of the CSRs).

#### Voting Agreements with Significant Valera Stockholders (Page 130)

In connection with the execution of the merger agreement, two Valera stockholders entered into voting agreements with Indevus: affiliates of Sanders Morris Harris, Inc., or SMH, and Psilos Group Partners II-S, L.P., or Psilos. As of the record date for the Valera special meeting, SMH and Psilos were the record and/or beneficial owners, respectively, of 5,449,980 and 728,037 shares of Valera common stock. These shares represent approximately 36.37% and 4.86%, respectively, and approximately 41.23% in the aggregate, of Valera s outstanding shares of common stock as of the record date. Pursuant to these voting agreements these stockholders have agreed, among other things and subject to limited exceptions, to vote all their Valera shares in favor of adoption of the merger agreement. The voting agreement with each of SMH and Psilos is included as *Annex D-1* and *Annex D-2*, respectively, to this joint proxy statement/prospectus.

#### **Recommendations of the Boards of Directors to Stockholders**

#### Indevus (Page 82)

After careful consideration, Indevus board of directors unanimously approved the merger agreement and the issuance of Indevus common stock and contingent stock rights pursuant to the merger agreement. Indevus board of directors determined that the merger and the transactions contemplated by the merger agreement are fair to, and in the best interests of, Indevus stockholders. **Indevus board of directors unanimously recommends that Indevus stockholders vote FOR the proposal to issue Indevus common stock and contingent stock rights pursuant to the merger agreement.** 

Indevus board of directors considered a number of factors in determining to approve the merger agreement and the issuance of Indevus common stock and contingent stock rights pursuant to the merger agreement. These considerations are described in the section entitled The Merger Indevus Reasons for the Merger beginning on page 82.

# Valera (Page 84)

After careful consideration, Valera s board of directors unanimously approved and adopted the merger agreement. Valera s board of directors determined that the merger and the transactions contemplated by the merger agreement are advisable and fair to, and in the best interests of, Valera s stockholders. Valera s board of directors unanimously recommends that the Valera stockholders vote FOR the proposal to adopt the merger agreement.

Valera s board of directors considered a number of factors in determining to approve and adopt the merger agreement and the merger. These considerations are described in the section entitled The Merger Valera's Reasons for the Merger beginning on page 84.

#### **Opinions of Financial Advisors**

#### Indevus (Page 86)

In connection with the merger, Indevus board of directors received an opinion from Indevus financial advisor, UBS Securities LLC, as to the fairness, from a financial point of view and as of the date of such opinion, to Indevus of the merger consideration to be paid by Indevus. For purposes of UBS opinion, the merger consideration refers to (i) the number of shares of Indevus common stock equal to the quotient of \$7.75 divided by the Indevus Common Stock Value and (ii) the CSRs. The full text of UBS written opinion, dated December 11, 2006, is attached to this joint proxy statement/prospectus as *Annex B*. Holders of Indevus common stock are encouraged to read this opinion carefully and in its entirety for a description of the assumptions made, procedures followed, matters considered and limitations on the review undertaken. **UBS opinion was provided to Indevus board of directors in its evaluation of the merger consideration from a financial point of view, does not address any other aspect of the merger and does not constitute a recommendation to any stockholder as to how to vote or act with respect to the merger.** 

#### Valera (Page 92)

In connection with the merger, Valera s board of directors considered the oral opinion of Banc of America Securities LLC, delivered on December 11, 2006, which was confirmed by a written opinion, dated December 11, 2006, that, as of the date of the opinion and based upon and subject to various assumptions and limitations set forth in the opinion, the merger consideration to be received by holders of Valera common stock (other than certain stockholders of Valera who have entered into voting agreements in connection with the merger) was fair, from a financial point of view, to such stockholders.

The full text of the written opinion of Banc of America Securities to Valera's board of directors which sets forth, among other things, the assumptions made, procedures followed, matters considered and limitations on the review undertaken, is attached as *Annex C* to this joint proxy statement/prospectus, and is incorporated into this joint proxy statement/prospectus by reference. Banc of America Securities provided its opinion for the information and assistance of Valera's board of directors in connection with its evaluation of the merger consideration. Banc of America Securities opinion does not address any other aspect of the merger and does not constitute a recommendation as to how any Valera stockholder should vote or act on any matters relating to the merger. Holders of Valera common stock are encouraged to, and should, read this opinion carefully and in its entirety.

#### Additional Interests of Valera Directors and Executive Officers in the Merger (Page 99)

In considering the recommendation of Valera s board of directors, Valera stockholders should be aware of the interests that certain Valera executive officers and directors may have in the merger that may be different from, or in addition to, their interests as Valera stockholders generally. These interests include:

severance and other payments and benefits to certain executive officers of Valera pursuant to existing change in control and employment agreements with Valera and a consulting arrangement between Dr. David S. Tierney, Valera s President and Chief Executive Officer, and Indevus during a transition period after the completion of the merger;

share issuances to Valera executive officers and directors in consideration of the cancellation of all options to purchase Valera common stock in connection with the merger;

employment agreements expected to be entered into between Indevus and certain officers of Valera, and, in the case of James C. Gale, Valera s chairman of the board, an expected membership on Indevus board of directors;

rights to continued director and executive officer indemnification and insurance coverage by Indevus after the merger for acts or omissions that occurred before the merger;

registration rights covering the shares of Indevus common stock acquired by SMH (and affiliated entities; James C. Gale, Valera s chairman of the board, is the chief investment officer of those SMH affiliated entities) in connection with the merger for resale under the Securities Act on a Registration Statement on Form S-3 to be filed by Indevus within 30 days following the effective time of the merger; and

severance payments to another executive officer of Valera pursuant to the Severance Pay Plan established by Indevus in connection with the merger.

As a result, the directors and executive officers of Valera may be more likely to recommend approval of the merger proposal than if they did not have these interests. The Valera board of directors was aware of these interests and considered them, among other matters, in reaching its decisions to declare the merger and the other transactions contemplated by the merger agreement advisable, to adopt the merger agreement and to recommend that Valera s stockholders vote in favor of adopting the merger agreement.

# Additional Interests of Indevus Directors and Officers in the Proposal to Amend Indevus Equity Incentive Plan and Employee Stock Purchase Plan

If either of the proposals to amend Indevus equity incentive plan to increase the number of shares of common stock reserved for issuance under the plan and to remove the 20% limitation on the types of awards that can be issued with respect to such additional shares is approved by Indevus stockholders, executive officers and directors of Indevus will be eligible to receive additional stock-based awards under the plan, including restricted and performance stock, stock options, phantom stock, stock bonus awards, and other awards (including stock appreciation rights). The additional awards may or may not be based on the performance of Indevus common stock, and no individual is guaranteed to receive any awards under the equity incentive plan. See the section entitled Proposal #4 Amendment No. 5 to Indevus 2004 Equity Incentive Plan, as Amended Description of Principal Features of the 2004 Plan beginning on page 243 for further information regarding the types of awards potentially available under the equity incentive plan.

If the proposal to amend Indevus employee stock purchase plan to increase the number of shares of common stock reserved for issuance under such plan is approved by Indevus stockholders, executive officers of Indevus will be eligible to purchase additional shares of common stock under the plan. See the section entitled Proposal #6 Amendment to Indevus 1995 Employee Stock Purchase Plan, as Amended Description of Principal Features of the 1995 Plan beginning on page 250 for further information regarding the stock purchase terms available under the stock purchase plan.

The Indevus compensation committee and board of directors were aware of these interests and considered them, among other matters, in reaching a decision to approve the amendments to the equity incentive plan and the stock purchase plan and to recommend that Indevus stockholders vote in favor of the amendments.

# Directors and Management of Indevus Following the Merger (Page 104)

James C. Gale, chairman of the board of directors of Valera and chief investment officer of the Corporate Opportunities Funds and Life Sciences Opportunities Fund, affiliates of SMH, has been nominated for election to Indevus board of directors at Indevus annual and special meeting. Otherwise, the existence and composition of the board of directors of Indevus will continue unchanged by the merger. Indevus executive officers will not change as a result of the merger.

# Material United States Federal Income Tax Consequences (Page 104)

The merger has been structured to qualify as a reorganization within the meaning of Section 368(a) of the Code. Assuming the merger qualifies as such a reorganization, for U.S. federal income tax purposes, holders of

Valera common stock whose shares of Valera common stock are exchanged in the merger for shares of Indevus common stock and CSRs will not recognize a gain or loss, except to the extent of cash, if any, received in lieu of a fractional share of Indevus common stock. In addition, a portion of any additional shares of Indevus common stock issued pursuant to the CSRs may be treated as taxable interest income to the Valera stockholders at the time such shares are issued.

It is a condition to the completion of the merger that Indevus and Valera receive written opinions from their respective counsel to the effect that the merger will qualify as a reorganization within the meaning of Section 368(a) of the Code. Neither Indevus nor Valera intends to waive this closing condition. In the event that either Indevus or Valera waives receipt of such opinion from its counsel, however, the waiving company will again solicit the approval of its stockholders after providing appropriate disclosure.

Tax matters are very complicated and the tax consequences of the merger to each Valera stockholder will depend on such stockholder s particular facts and circumstances.

Valera stockholders are urged to consult their tax advisors to understand fully the tax consequences to them of the merger.

#### **Overview of the Merger Agreement (Page 112)**

#### Conditions to Completion of the Merger (Page 126)

The completion of the merger depends on the satisfaction or waiver, where permitted by the merger agreement, of a number of conditions, including the following:

adoption of the merger agreement by Valera stockholders and approval of the issuance of Indevus common stock by Indevus stockholders;

absence of any order, statute or regulation prohibiting the merger;

authorization by Nasdaq of the listing on The Nasdaq Global Market of the shares of Indevus common stock issuable to Valera stockholders in the merger and the shares of Indevus common stock issuable upon conversion of the CSRs;

the Securities and Exchange Commission, or SEC, declaring effective the registration statement filed on Form S-4, of which this joint proxy statement/prospectus is a part;

absence of any governmental action challenging or seeking to enjoin the merger;

receipt of opinions of counsel to Valera and Indevus that the merger will qualify as a tax-free reorganization; and

other customary conditions specified in the merger agreement. No Solicitation by Valera (Page 121)

Subject to certain exceptions, the merger agreement precludes Valera or any of its subsidiaries, whether directly or indirectly through officers, directors, employees, agents or representatives, from soliciting, initiating, encouraging, or taking any action to facilitate any inquiries that could reasonably be expected to lead to, entering into any agreement with respect to, or participating in any discussions or negotiations regarding, any third party s proposal with respect to the acquisition of assets that constitute 15% or more of the revenues, net income, EBITDA (earnings before interest expense, taxes, depreciation and amortization) or assets of Valera and its subsidiaries, taken as a whole, or of an equity interest representing a 15% or greater economic interest in Valera or any of its subsidiaries.

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However, under certain circumstances, Valera and its board of directors may furnish non-public information to, and enter into discussions or negotiations with, a third party in connection with an unsolicited written acquisition proposal that it determines (after consultation with outside counsel and its financial advisor) to be, or to be reasonably expected to lead to, a superior proposal, as defined in the merger agreement, if a majority of Valera s board of directors determines (after receiving the advice of outside counsel) that such action is necessary for it to comply with its fiduciary duties to its stockholders and other conditions specified in the merger agreement are satisfied.

# Termination of the Merger Agreement (Page 127)

Indevus and Valera can mutually agree to terminate the merger agreement at any time without completing the merger. In addition, either Indevus or Valera may also terminate the merger agreement if the merger is not completed by August 11, 2007, or under other circumstances set forth in the merger agreement and described in this document.

# Termination Fees and Expenses (Page 128)

Indevus and Valera will each bear one-half of the expenses incurred in connection with the preparation of this joint proxy statement/prospectus and otherwise, generally, will bear their own expenses related to the merger. In addition, upon termination of the merger agreement under specified circumstances, Valera or Indevus may be required to pay the other a termination fee of \$5,000,000. The merger agreement also provides that under specified circumstances where the termination fee is not otherwise payable, Valera or Indevus may be required to reimburse the non-terminating party for up to \$3,000,000 of reasonable out-of-pocket expenses. Any expenses reimbursed by Valera or Indevus will be credited against the termination fee if the termination fee subsequently becomes payable by that party.

# Accounting Treatment (Page 107)

Indevus will account for the merger as a purchase of a business under United States generally accepted accounting principles, or GAAP. This means that Indevus will allocate the purchase price to the fair value of Valera s assets and liabilities, including intangible assets, at the acquisition date, with the excess purchase price being recorded as goodwill. The results of operations of Valera will be included in Indevus results from the date of acquisition.

# **Regulatory Matters Related to the Merger (Page 108)**

Indevus and Valera are not aware of any material governmental or regulatory requirements that must be complied with regarding the merger, other than the effectiveness of the registration statement of which this joint proxy statement/prospectus is a part and compliance with applicable provisions of Delaware law.

# Appraisal Rights for Valera Stockholders (Page 108)

Under Delaware law, Valera stockholders have the right to dissent from the merger and to receive payment in cash for the fair value of their shares of Valera common stock, as determined by the Delaware Chancery Court. This right of appraisal is subject to a number of restrictions and technical requirements. Generally, in order to exercise appraisal rights, a Valera stockholder must:

send to Valera a written demand for appraisal in compliance with Delaware law before the vote on the merger; and

not vote in favor of the merger.

**Merely voting against the merger will not protect a Valera stockholder s rights to appraisal.** In order to protect such rights, the stockholder must adhere to all of the requirements set forth under Delaware law. The requirements under Delaware law for exercising appraisal rights are described in further detail in the section entitled Appraisal Rights for Valera Stockholders beginning on page 108. The relevant section of Delaware law regarding appraisal rights is reproduced and included as *Annex H* to his joint proxy statement/prospectus. **If you are a Valera stockholder and you vote on the merger, you will waive your rights to seek appraisal of your shares of Valera common stock under Delaware law.** 

Indevus stockholders are not entitled to dissenters or appraisal rights under Delaware law in connection with the merger.

#### How the Rights of Valera Stockholders Will Differ as Indevus Stockholders (Page 215)

Although both Indevus and Valera are Delaware corporations governed by the General Corporation Law of the State of Delaware, the rights of Indevus stockholders are different in some respects from the rights of Valera stockholders because of differences in the respective certificates of incorporation and bylaws of Indevus and Valera. Therefore, Valera stockholders will have different rights as stockholders once they become Indevus stockholders. These differences are described in detail in the section entitled Comparison of Valera Stockholder Rights and Indevus Stockholder Rights beginning on page 215.

### Listing of Indevus Common Stock and Delisting of Valera Common Stock (Page 111)

Indevus will apply to have the shares of Indevus common stock issued in the merger and the shares of common stock issuable upon conversion of CSRs approved for listing on The Nasdaq Global Market, where shares of Indevus common stock currently are traded under the symbol IDEV. Indevus will not apply to have the CSRs themselves approved for listing on any securities market. If the merger is completed, Valera common stock will no longer be listed on The Nasdaq Global Market and will be deregistered under the Securities Exchange Act of 1934, which we refer to as the Exchange Act, and Valera will no longer file periodic reports with the SEC.

#### **Comparative Stock Price Information (Page 32)**

Shares of Indevus common stock are listed on The Nasdaq Global Market under the symbol IDEV. Shares of Valera common stock are listed on The Nasdaq Global Market under the symbol VLRX. On December 11, 2006, the last full trading day prior to the public announcement of the proposed merger, Indevus common stock closed at \$7.86 per share and Valera common stock closed at \$5.41 per share. On March 9, 2007, the last full trading day prior to the date of this joint proxy statement/prospectus, Indevus common stock closed at \$6.52 per share and Valera common stock closed at \$7.97 per share. Indevus and Valera stockholders should obtain current market price information for Indevus common stock and Valera common stock before considering and voting on the applicable merger proposals.

# The Stockholders Meetings

# The Indevus Annual and Special Meeting (Page 69)

The Indevus annual and special meeting will be held on April 17, 2007, at 11:00 a.m., local time, at The Conference Center at Waltham Woods, 860 Winter Street, Waltham, MA 02451. At the Indevus annual and special meeting, Indevus stockholders will be asked to:

Approve the issuance of Indevus common stock and contingent stock rights pursuant to the merger agreement;

Elect eight members of Indevus board of directors to serve until the 2008 annual meeting of stockholders and until their successors are elected and qualified;

Approve an amendment to Indevus Restated Certificate of Incorporation to increase the number of authorized shares of Indevus common stock from 120 million to 200 million;

Approve an amendment to Indevus 2004 Equity Incentive Plan to increase the number of shares of Indevus common stock reserved for issuance under the plan from 6,000,000 to 9,000,000;

Approve an amendment to Indevus 2004 Equity Incentive Plan to remove the 20% limitation on the number of certain types of awards that can be made with respect to the additional 3,000,000 shares proposed to be added plan as set forth above;

Approve an amendment to Indevus 1995 Stock Purchase Plan to increase the number of shares of Indevus common stock available for purchase under the plan from 800,000 to 1,050,000; and

Ratify the appointment of PricewaterhouseCoopers LLP as Indevus independent registered public accounting firm. The approval of the issuance of Indevus common stock and contingent stock rights pursuant to the merger agreement is a condition to the completion of the merger. Accordingly, if Indevus stockholders wish to approve the merger, they must approve this proposal.

Indevus stockholders also will be asked to transact any other business that may be properly brought before the annual and special meeting or any adjournments or postponements of the annual and special meeting.

You may vote at the Indevus annual and special meeting if you owned shares of Indevus common stock, Series B Preferred Stock or Series C Preferred Stock at the close of business on March 12, 2007. On that date, there were outstanding and entitled to vote 56,202,160 shares of Indevus common stock, 239,425 shares of Series B Preferred Stock and 5,000 shares of Series C Preferred Stock, which, together (and on an as-if-converted basis with respect to the preferred stock), are entitled to an aggregate of 56,771,010 votes on all matters at the annual and special meeting, other than the election of directors for which preferred stock is not eligible to vote.

The proposals require different percentages of votes in order to approve them:

The issuance of Indevus common stock and contingent stock rights pursuant to the merger agreement, the amendments to Indevus 2004 Equity Incentive Plan, the amendment to Indevus 1995 Employee Stock Purchase Plan and the ratification of PricewaterhouseCoopers LLP as Indevus independent registered public accounting firm, require approval by the affirmative vote of a majority of the total number of votes cast on the particular proposal (with the Indevus common stock and preferred stock voting together as a single class);

The election of eight directors to Indevus board of directors requires the affirmative vote of a plurality of votes cast by the holders of Indevus common stock (with preferred stock not entitled to vote on this matter); and

Approval of the amendment to Indevus Restated Certificate of Incorporation requires the affirmative vote of both (i) a majority of the total number of votes of Indevus common stock and preferred stock outstanding and entitled to vote, voting together as a single class (regardless of whether such holders are present in person or represented by proxy at the annual and special meeting) and (ii) a majority of the outstanding shares of Indevus common stock, voting separately as a class.

As of the close of business on the record date for the annual and special meeting, the directors and executive officers of Indevus collectively beneficially owned approximately 8,742,264 shares of Indevus common stock inclusive of shares subject to stock options that may be exercised within 60 days following that date. Such shares represented approximately 13.48% of the total Indevus voting power as of such date.

## The Valera Special Meeting (Page 75)

The Valera special meeting will be held on April 17, 2007, at 10:00 a.m., local time, at Valera s offices at 7 Clarke Drive, Cranbury, NJ 08512. At the Valera special meeting, Valera stockholders will be asked to adopt the merger agreement and to transact any other business that may be properly brought before the special meeting or any adjournments or postponements of the special meeting.

You may vote at the Valera special meeting if you owned shares of Valera common stock at the close of business on March 12, 2007. On that date, there were outstanding and entitled to vote on all matters at the special meeting 14,985,670 shares of Valera common stock.

Adoption of the merger agreement requires the affirmative vote of a majority of the shares of Valera common stock outstanding on the record date and entitled to vote at the special meeting (regardless of whether such shares are present in person or represented by proxy at the special meeting).

As of the close of business on the record date for the special meeting, the directors and executive officers of Valera collectively beneficially owned approximately 9,093,070 shares of Valera common stock or approximately 58% of the outstanding shares of Valera common stock (inclusive of shares subject to stock options that may be exercised within 60 days following that date).

### SELECTED HISTORICAL CONSOLIDATED FINANCIAL DATA OF INDEVUS

The following information is being provided to aid in your analysis of the financial aspects of the merger. Indevus derived its financial information from audited financial statements for fiscal years 2002 through 2006 and from unaudited financial statements for the three months ended December 31, 2006 and 2005.

In the opinion of Indevus management, this unaudited interim period information reflects all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of the results of operations and financial condition for the three months ended December 31, 2006 and 2005. Results for interim periods should not be considered indicative of results for any other period or for the year. This information is only a summary. You should read it along with Indevus historical audited financial statements and related notes and the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations contained in Indevus annual reports, quarterly reports and other information on file with the SEC and incorporated by reference into this joint proxy statement/prospectus. See the section entitled Where You Can Find More Information beginning on page 257.

#### **Consolidated Statements of Operations:**

	December 31,				Fiscal Years Ended Septer				ember 30,				
	20	06		2005	(	2006		2005		2004		2003	2002
Statement of Operations Data:					(11	thousands	, ex	cept per sha	are a	amounts)			
Revenues:													
Product revenue	\$	5,257	\$	3,429	\$	26,738	\$	14,269	\$	9,740	\$	4,316	\$ 3,439
Contract and license fees		7,894		5,545		23,714		19,067		8,986		929	968
Total revenues	1	3,151		8,974		50,452		33,336		18,726		5,245	4,407
Cost of product revenue		4,276		1,870		19,692		8,593		7,950		1,073	733
Research and development		9,919		10,320		43,203		30,597		23,303		24,466	13,614
Marketing, general and administrative		9,003		8,308		36,009		41,983		51,916		11,105	8,090
Loss from operations	(1	0,047)		(11,524)		(48,452)		(47,837)		(64,443)		(31,399)	(18,030)
Investment Income		1,040		886		3,505		3,142		1,396		664	987
Interest expense		1,292		1,292		5,170		5,170		5,170		1,077	
Loss before income taxes	(1	0,299)		(11,930)		(50,554)		(50,047)		(68,212)		(31,812)	(17,586)
Provision for income taxes								(3,171)					
Net loss <sup>1</sup>	(1	0,299)		(11,930)		(50,554)		(53,218)		(68,212)		(31,812)	(17,586)
Preferred stock dividends						35		35		35		35	35
Net loss attributable to common stockholders	(1	0,299)		(11,930)		(50,589)		(53,253)		(68,247)		(31,847)	(17,621)
Loss per common share from													
operations-diluted		(0.18)		(0.25)		(1.02)		(1.13)		(1.43)		(0.68)	(0.38)
Net loss per common share-basic and diluted	\$	(0.18)	\$	(0.25)	\$	(1.02)	\$	(1.13)	\$	(1.43)	\$	(0.68)	\$ (0.38)
Weighted average common shares	5	5,847		47,166		49,411		46,977		47,542		46,930	45,896

Three Months Ended

	December 31,						
	2006	2005	2006	2005	2004	2003	2002
			(Am	ounts in thousa	nds)		
Balance Sheet Data:							
Working capital	\$ 51,298	\$ 65,186	\$ 54,876	\$ 79,233	\$ 131,288	\$ 73,866	\$ 34,876
Total assets	91,452	99,568	92,307	112,531	173,838	90,071	43,931
Convertible Notes, long-term	72,000	72,000	72,000	72,000	72,000	72,000	
Total liabilities including deferred revenue	224,448	225,629	216,511	227,667	236,868	83,817	6,700
Accumulated deficit	(482,974)	(434,051)	(472,675)	(422,121)	(368,903)	(300,691)	(268,879)
Total stockholders equity (deficit)	(133,122)	(126,067)	(124,330)	(115,142)	(63,038)	6,241	37,218

(1)

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The Company adopted SFAS 123R on a modified prospective basis beginning in fiscal 2006. The expense is determined on an individual employee basis and subsequently allocated to their respective departments.

# SELECTED HISTORICAL FINANCIAL DATA OF VALERA

The following information is being provided to aid in your analysis of the financial aspects of the merger. Valera derived its financial information from audited financial statements for fiscal years 2002 through 2006. The information is only a summary. You should read it along with Valera's historical audited financial statements and related notes beginning on page 184 and the section entitled Valera Management's Discussion and Analysis of Financial Condition and Results of Operations of Valera' beginning on page 168.

### **Statements of Operations:**

		Year I	Ended Decembe	er 31,	
	2006	2005	2004	2003	2002
		· · ·	, except per sha		
Net product sales	\$ 17,845	\$ 26,798	\$ 5,511	\$7	\$ 15
Licensing revenue	121	34	135		
Total net revenue	17,966	26,832	5,646	7	15
Operating costs and expenses					
Cost of product sales	5,107	5,966	608		
Research and development	7,574	5,930	6,376	5,230	4,320
Selling and marketing	12,139	10,754	5,025	509	270
General and administrative	8,154	5,500	5,897	1,838	1,324
Amortization of intangible assets	79				
Total operating expenses	33,053	28,150	17,906	7,577	5,914
Loss from operations	(15,087)	(1,318)	(12,260)	(7,570)	(5,899)
Interest income (expense), net	941	49	(6)	13	16
Loss before income taxes	(14,146)	(1,269)	(12,266)	(7,557)	(5,883)
(Benefit from) provision for income taxes	(207)	75	(243)		
Net loss	(13,939)	(1,344)	(12,023)	(7,557)	(5,883)
Deemed dividend			(5,861)	(1,139)	
Net loss attributable to common stockholders	\$ (13,939)	\$ (1,344)	\$ (17,884)	\$ (8,696)	\$ (5,883)
Basic and diluted net loss attributable to common stockholders per share	\$ (1.03)	\$ (0.81)	\$ (10.73)	\$ (5.22)	\$ (3.53)
Weighted average shares outstanding basic and diluted	13,580	1,667	1,667	1,667	1,667

	As of December 31,					
	2006	2005	2004	2003	2002	
			(in thousands)			
Balance Sheet Data:						
Cash and cash equivalents	\$ 14,069	\$ 2,340	\$ 5,053	\$ 5,241	\$ 641	
Working capital	17,597	2,845	8,306	4,585	(404)	
Total assets	31,965	16,532	13,667	6,665	1,296	
Long-term liabilities	313	300	17	33	67	
Convertible preferred stock		39,925	39,925	20,469	6,604	
Total stockholders equity (deficit)	25,731	(31,593)	(29,887)	(15,158)	(6,465)	

# Selected Quarterly Financial Data (Unaudited) of Valera:

	2006 Quarters Ended						
	March 31,	June 30,	Sept	ember 30,	Dece	ember 31,	
		(In thousands, ex	cept per	share amoun	ıts)		
Total net revenue	\$ 5,532	\$ 6,220	\$	3,013	\$	3,201	
Cost of product sales	1,461	1,653		883		1,110	
Total operating expenses	7,818	9,246		8,002		7,987	
Loss from operations	(2,286)	(3,026)		(4,989)		(4,786)	
Provision for (benefit from) income taxes	10	10		(36)		(191)	
Net loss attributable to common shareholders	(2,112)	(2,742)		(4,684)		(4,401)	
Basic and diluted net loss attributable to common shareholders per							
common share	\$ (0.22)	\$ (0.18)	\$	(0.31)	\$	(0.29)	

	2005 Quarters Ended						
	March 31,	June 30,	Sept	tember 30,	Dece	ember 31,	
		(In thousands,	except p	er share amou	ints)		
Total net revenue	\$ 7,695	\$ 10,286	\$	3,678	\$	5,173	
Cost of product sales	1,023	2,951		809		1,183	
Total operating expenses	5,972	8,777		6,805		6,596	
Income (loss) from operations	1,723	1,509		(3,127)		(1,423)	
Provision for (benefit from) income taxes	160	140		(300)		75	
Net income (loss) attributable to common shareholders	1,577	1,382		(2,808)		(1,495)	
Basic net income (loss) attributable to common shareholders per							
common share	\$ 0.95	\$ 0.83	\$	(1.68)	\$	(0.90)	
Diluted net income (loss) attributable to common shareholders per							
common share	\$ 0.14	\$ 0.12	\$	(1.68)	\$	(0.90)	

### UNAUDITED PRO FORMA COMBINED CONSOLIDATED FINANCIAL INFORMATION

The accompanying unaudited pro forma combined consolidated financial statements present financial information from the Indevus and Valera unaudited pro forma combined consolidated statements of operations for the years ended September 30, 2006 for Indevus and December 31, 2006 for Valera and for the three months ended December 31, 2006 for Indevus and Valera and the unaudited pro forma combined consolidated balance sheet as of December 31, 2006 is based on the historical balance sheets of Indevus and Valera as of that date. The unaudited pro forma combined consolidated balance sheet as of December 31, 2006 is presented as if the merger had occurred on the first day of the period (*i.e.*, October 1, 2005). The unaudited pro forma combined consolidated balance sheet gives effect to the transaction as if it occurred on December 31, 2006. The unaudited pro forma combined consolidated financial data are based on estimates and assumptions, which are preliminary and subject to change, as set forth in the notes to such statements and which are provided for informational purposes only. The unaudited pro forma combined consolidated, nor are they necessarily indicative of future financial position or operating results. This information should be read in conjunction with the historical financial statements and related notes of Indevus and Valera included in or incorporated by reference into this joint proxy statement/prospectus.

# UNAUDITED PRO FORMA COMBINED CONSOLIDATED BALANCE SHEET

# (Amounts in thousands except share data)

	Histor	9		
	Indevus	Valera	Pro form Adjustments	Combined
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 73,367	\$ 14,069	\$	\$ 87,436
Marketable securities				
Accounts receivable, net	5,417	2,661		8,078
Inventories, net	1,585	5,911	950(C)	8,446
Prepaid and other current assets	3,671	877		4,548
Total current assets	84,040	23,518	950	108,508
Property and equipment, net	904	7,849	405(C)	9,158
Insurance claim receivable	1,258			1,258
Prepaid debt issuance costs	1,018			1,018
Inventories, net	1,812			1,812
Intangible assets, net		446	31,604(A)	32,050
Other assets	2,420	152	1,200(C)	3,772
Goodwill			29,770(E)	29,770
Total assets	\$ 91,452	\$ 31,965	\$ 63,929	\$ 187,346
LIABILITIES				
Current liabilities:				
Accounts payable	\$ 2,384	\$ 2,594	\$	\$ 4,978
Accrued expenses	12,517	3,318	10,956(F),(G)	26,791
Accrued interest	2,075			2,075
Deferred revenue	15,766			15,766
Capital lease obligations current		9		9
Total current liabilities	32,742	5,921	10,956	49.619
Convertible notes	72,000			72,000
Deferred revenue	117,561	300	(200)(C)	117,661
Capital lease obligations long term		13		13
Other	2,145		150(C)	2,295
Minority interest	126			126
STOCKHOLDERS DEFICIT				
Convertible preferred stock				
Series B	3,000			3,000
Series C	500		/1 =\ /= \	500
Common stock, \$.001 par value	56	15	(15)(H)	56
	246 206	70.01/	18(H)	18
Additional paid-in-capital	346,296	79,316	(79,316)(H)	346,296
			121,537(H)	121,537
	(400.074)	(52 (00)	4,602(H)	4,602
Accumulated deficit	(482,974)	(53,600)	53,600(H)	(482,974)
			(40,000)(I)	(40,000)
			(6,194)(F),(G)	(6,194)
			(1,208)(J)	(1,208)

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Total stockholders deficit	(133,122)	25,731	53,023	(54,368)
Total liabilities and stockholders deficit	\$ 91,452	\$ 31,965	\$ 63,929	\$ 187,346

# UNAUDITED PRO FORMA COMBINED CONSOLIDATED STATEMENTS OF OPERATIONS (Amounts in thousands except per share data)

	For the twelve months ended (1)				
	Historical Indevus Valera		Pro form		
D	Indevus	Valera	Adjustments	Combined	
Revenues: Product revenue	¢ 06 729	¢ 17.045	¢	¢ 44.592	
	\$ 26,738	\$ 17,845	\$	\$ 44,583	
Contract and license fees	23,714	121		23,835	
Total revenues	50,452	17,966		68,418	
Costs and Expenses:					
Cost of product revenue	19,692	5,107	3,078(B),(D)	27,877	
Research and development	43,203	7,574		50,777	
Marketing, general and administrative	36,009	20,372		56,381	
Total costs and expenses	98,904	33,053	3,078	135,035	
Loss from operations	(48,452)	(15,087)	(3,078)	(66,617)	
Investment income	3,505			3,505	
Interest (expense) income, net	(5,170)	941		(4,229)	
Minority interest and other	(437)			(437)	
Loss before income taxes	(50,554)	(14,146)	(3,078)	(67,778)	
Provision for (benefit from) income taxes		(207)	(K)	(207)	
Net loss	\$ (50,554)	\$ (13,939)	\$ (3,078)	\$ (67,571)	
1001000	\$ (50,551)	$\varphi(10,000)$	\$ (3,070)	\$ (07,371)	
Net loss per common share, basic and diluted	\$ (1.02)	\$ (1.03)	\$ (0.17)	\$ (1.00)	
Weighted average common shares outstanding, basic and diluted	49,411	13,580	18,194(L)	67,605	
weighted average common shares outstanding, basic and unuted	79,711	15,500	10,19 <del>4</del> (L)	07,005	

(1) As reported in Indevus audited Annual Report on Form 10-K for the year ended September 30, 2006. As reported in Valera s audited Annual Report on Form 10-K for the year ended December 31, 2006.

#### UNAUDITED PRO FORMA COMBINED CONSOLIDATED STATEMENTS OF OPERATIONS (Continued)

#### (Amounts in thousands except per share data)

	For the three months ended December 31, 2006					
	Histo Indevus	Pro fo Adjustments	rma Combined			
Revenues:	inde vus	Valera	Aujustinents	Combilieu		
Product revenue	\$ 5,257	\$ 3,196	\$	\$ 8,453		
Contract and license fees	7,894	5		7,899		
Total revenues	13,151	3,201		16,352		
Costs and Expenses:	15,151	5,201		10,332		
Cost of product revenue	4,276	1,110	532(B),(D)	5,918		
Research and development	9,919	1,860	332(B),(B)	11,779		
Marketing, general and administrative	9,003	5,017		14,020		
Total costs and expenses	23,198	7,987	532	31,717		
Loss from operations	(10,047)	(4,786)	(532)	(15,365		
Investment income	1.040	(1,100)	()	1,040		
Interest (expense) income, net	(1,292)	194		(1,098		
Minority interest and other						
Loss before income taxes	(10,299)	(4,592)	(532)	(15,423)		
Provision for (benefit from) income taxes	(,)	(191)	(K)	(191)		
Net loss	\$ (10,299)	\$ (4,401)	\$ (532)	\$ (15,232)		
Net loss per common share, basic and diluted	\$ (0.18)	\$ (0.29)	\$ (0.03)	\$ (0.21)		
Weighted average common shares outstanding, basic and diluted Note 1:	55,847	14,935	18,194(L)	74,041		

Note 1:

The allocation of the purchase price is preliminary and is based upon a preliminary valuation of tangible and intangible assets acquired and liabilities assumed. The purchase price allocation included within these unaudited pro forma combined consolidated financial statements is based upon a preliminary estimated purchase price of approximately \$129.7 million. The exchange ratio for the merger will be determined shortly before the merger, and will be calculated based upon the volume weighted average of the closing prices of Indevus common stock during the 25 trading days ending five trading days prior to the date of the stockholders meeting to vote on the merger. For purposes of the unaudited pro forma condensed consolidated financial statements, we have assumed an exchange ratio for the merger of 1.1687 shares of Indevus common stock for each share of Valera common stock. Such exchange ratio was calculated assuming that the volume weighted average of the closing prices of Indevus common stock used to derive the exchange ratio was \$6.63, which incorporates the average trading price of Indevus common stock for the 25 trading days ending five trading days prior to March 1, 2007 (a date selected by management to estimate the preliminary purchase price for the purpose of filing the registration statement of which this joint proxy statement/prospectus is part), and which assumes a \$6.94 fair value of the Indevus common stock based on the average trading price of the Indevus common stock for the two full trading days prior to and subsequent to March 1, 2007. The merger also provides the Valera option holders the right to receive shares of Indevus stock as consideration for the cancellation of their Valera stock options. The number of Indevus shares which will be issued in exchange for such options also will be determined shortly before we complete the merger. For purposes of the unaudited pro forma condensed consolidated financial statements, we have assumed that the Valera options will be exchanged for approximately 681,000 shares of Indevus common stock, at a fair value of \$6.76, based on the closing price of Indevus common stock on March 1, 2007, which aggregates \$4.6 million, of which \$3.4 million is additional purchase price and \$1.2 million is non-cash

compensation expense attributed to the issuance of Indevus shares to unvested Valera option holders. The purchase price also includes the estimated transaction costs to be paid by Indevus in connection with the merger. The preliminary purchase consideration is as follows:

Issuance of Indevus common stock to Valera stockholders (17.5 million shares at \$6.94 per share)	\$ 121,555
Fair value of Indevus common stock to be issued as consideration for cancellation of outstanding Valera	
stock options	3,393
Estimated Indevus transaction costs	4,762
Total preliminary purchase price	\$ 129,710

Although the Valera stockholders will also receive CSRs, and the option holders who consent to the proposed treatment of such options will receive an unfunded and unsecured promise to receive shares of Indevus common stock pursuant to a formula specified in the Merger Agreement (CSR Equivalents), such CSRs and CSR Equivalents are contingent consideration, which is not reflected in the preliminary purchase price noted above but which will be reflected as additional purchase price when and if such contingencies are resolved and the CSRs and CSR Equivalents become issued or issuable. If all of the CSRs and CSR Equivalents were to be converted into Indevus common stock, based on the preliminary exchange ratios noted above, there would be approximately \$56.6 million of additional purchase price resulting from this contingent consideration.

If the Indevus Common Stock Value is greater than \$8.05 or less than \$6.59, then the exchange ratio will be fixed at 0.9626 and 1.1766 shares, respectively, of Indevus common stock for each share of Valera common stock. Had such fixed ratios been considered in the preliminary purchase price consideration noted above, the number of Indevus issued shares would have ranged from 14.4 million to 17.6 million, and the fair value of these shares would have ranged from \$100.1 million to \$122.4 million, at an assumed fair value of \$6.94.

Indevus has not completed its assessment of the fair value of the assets and liabilities assumed of Valera and the related business integration plans. The table below represents a preliminary allocation of the total consideration to Valera s tangible and intangible assets and liabilities based on management s preliminary estimate of their respective fair values as of the date of the merger.

The amount of in-process research and development, identifiable intangible assets, and goodwill, as well as the estimated useful lives of these assets, will be determined upon completion of an appraisal and therefore, may be different from the amounts presented within these unaudited pro forma combined financial statements. To the extent the amounts and estimated useful lives are different, the unaudited pro forma combined consolidated financial statements could change significantly (i.e. upon receipt of FDA approval of one of Valera s existing NDA applications prior to close of the merger). Assuming the purchase consideration does not change, the effect of any changes to the value of Valera s net assets acquired would directly impact goodwill. The preliminary purchase price allocation is as follows (U.S. dollars, in thousands):

Net tangible assets acquired	\$ 27,890
In-process research and development	40,000
Identifiable intangible assets	32,050
Goodwill	29,770
Total preliminary consideration	\$ 129,710

Note 2:

Adjustments included in the unaudited pro forma combined consolidated balance sheets and unaudited pro forma combined consolidated statements of operations are summarized as follows:

A. To record the estimated valuation of identifiable intangible assets acquired and to eliminate Valera s historical intangible assets. The fair value of identifiable intangible assets of \$32.1 million was estimated using a discounted cash flow model.

B. To record amortization expense for identifiable intangible assets using an average estimated useful life of 14-18 years.

C. To record the fair value of tangible assets acquired and liabilities assumed, including fixed assets, inventory, investment in Spepharm Holding B.U., or Spepharm, deferred revenue and unfavorable lease obligations.

D. To record additional depreciation expense of \$140,000 and \$35,000 for the twelve months ended September 30, 2006 and for the three months ended December 31, 2006, respectively, resulting from the fixed asset fair value adjustments. To record additional cost of sales of \$1 million for the twelve months ended September 30, 2006 resulting from the inventory fair value adjustment.

E. To record goodwill related to the merger of \$29.8 million. Goodwill represents the difference between total preliminary consideration and identifiable tangible and intangible assets acquired, net of liabilities assumed.

F. To record the accrual of \$4.5 million of Indevus transaction costs, included as a component of total purchase price, and \$3.8 million of Valera transaction costs, expensed by Valera. These costs include, but are not limited to, fees for financial advisors, accountants and attorneys and other related costs.

G. To record the accrual of severance payments made by Indevus to certain Valera employees, estimated at \$272,000, in addition to the accrual of severance costs for certain Valera employees to be paid by Valera prior to the close of the merger, estimated at \$2.4 million. Because the \$2.4 million paid by Valera will be expensed prior to the consummation of the deal and will not have a continuing impact, it is not reflected in the pro forma condensed statement of operations.

H. To eliminate Valera's historical stockholders equity accounts. These adjustments also reflect the issuance of 18.2 million shares of Indevus \$0.001 par value common stock with an estimated value of \$126.2 million in exchange for all common stock of Valera, including an adjustment of \$4.6 million to additional paid-in-capital to reflect the fair value of all Indevus shares to be issued by Indevus in the merger as consideration for the cancelled Valera options.

I. To record the estimated fair value of in-process research and development acquired in the merger. Because this expense is directly attributable to the acquisition and will not have a continuing impact, it is not reflected in the pro forma condensed statement of operations. However, this item will be recorded as an expense immediately following the completion of the merger.

J. To record the noncash stock based compensation expense substantially related to the issuance of Indevus shares to unvested Valera option holders. This expense is a component of the \$4.6 million of total value attributed to the fair value of the Indevus shares issued as consideration for the cancellation of Valera options.

K. The pro forma adjustments do not include any related income tax effects as Indevus provides a full valuation allowance on its deferred tax assets.

L. To record the issuance of Indevus shares to Valera stockholders and option holders in connection with the merger. Valera shares were exchanged using the balance of shares outstanding at the measurement date of March 1, 2007.

#### **COMPARATIVE PER SHARE INFORMATION**

The following table sets forth for the Indevus and Valera common stock certain historical, pro forma combined consolidated and pro forma equivalent per share financial information. The pro forma data in the table are derived from, and should be read in conjunction with, the

Unaudited Pro Forma Combined Consolidated Financial Information and related notes thereto beginning on page 25. Indevus historical per share information is derived from the audited consolidated financial statements for the year ended September 30, 2006 contained in Indevus Annual Report on Form 10-K for the year ended September 30, 2006 and the unaudited consolidated interim financial statements for the three months ended December 31, 2006 contained in Indevus Quarterly Report on Form 10-Q for the quarter ended December 31, 2006, both of which are incorporated by reference into this joint proxy statement/prospectus. Valera s historical per share information is derived from the audited financial statements for the year ended December 31, 2006 contained elsewhere in this document.

The unaudited pro forma combined consolidated per share information does not purport to represent what the actual results of operations of the combined company would have been had the merger been in effect for the periods described below or to project the future results of the combined company after the merger.

Per Common Share Data	Indevus Historical	Valera Historical	Unaudited Pro Forma Combined Consolidated	Pro Forma Equivalent Per Valera Share (3)
For the twelve months ended September 30, 2006 and December 31,				
2006 (1)				
Net income (loss)				
Basic	\$ (1.02)	\$ (1.03)	\$ (1.00)	\$ (1.17)
Diluted	\$ (1.02)	\$ (1.03)	\$ (1.00)	\$ (1.17)
As of and for the three months ended December 31, 2006				
Net income (loss)				
Basic	\$ (0.18)	\$ (0.29)	\$ (0.21)	\$ (0.24)
Diluted	\$ (0.18)	\$ (0.29)	\$ (0.21)	\$ (0.24)
Book value (2)	\$ (2.37)	\$ 1.72	\$ (0.73)	\$ (0.85)

(1) For Indevus, as of and for the fiscal year ended September 30, 2006. For Valera, as of and for the fiscal year ended December 31, 2006.

(2) The historical book value per share is calculated by dividing stockholders equity by the number of shares outstanding at period end. The unaudited pro forma combined consolidated net book value per common share is computed by dividing the pro forma combined consolidated common stockholders equity by the pro forma combined consolidated number of Indevus common shares outstanding at period end, assuming the merger had occurred as of that date.

(3) The pro forma equivalent per Valera share is calculated by multiplying the pro forma consolidated amounts by the assumed exchange ratio of 1.1687 shares of Indevus common stock for each share of Valera common stock, in order to equate the pro forma consolidated amounts to the respective values for one share of Valera common stock.

#### COMPARATIVE STOCK PRICES AND DIVIDENDS

Indevus common stock is listed on The Nasdaq Global Market under the symbol IDEV. Valera common stock is listed on The Nasdaq Global Market under the symbol VLRX. Valera began trading on The Nasdaq Global Market on February 3, 2006. The following table sets forth, for the periods indicated, the high and low sale prices per share of Indevus and Valera common stock as reported on The Nasdaq Global Market (and its predecessor markets).

	High	Low
Indevus		
Fiscal Year 2005		
First Quarter	\$ 7.45	\$ 5.85
Second Quarter	6.08	2.73
Third Quarter	3.78	2.41
Fourth Quarter	3.42	2.55
Fiscal Year 2006		
First Quarter	\$ 5.43	\$ 2.50
Second Quarter	6.75	4.92
Third Quarter	6.32	4.25
Fourth Quarter	6.48	4.99
Fiscal Year 2007		
First Quarter	8.06	5.58
Second Quarter (through March 9, 2007)	7.48	6.18
Valera		
Fiscal Year 2006		
First Quarter (commencing February 3, 2006)	\$ 12.00	\$ 7.75
Second Quarter	10.40	7.52
Third Quarter	8.54	5.50
Fourth Quarter	8.42	4.49
Fiscal Year 2007		
First Quarter (through March 9, 2007)	8.61	7.56

The following table presents the per share closing prices of Indevus and Valera common stock on a historical basis and Valera common stock on a proforma equivalent basis on December 11, 2006, the last business day before Indevus and Valera publicly announced the execution and delivery of the merger agreement, and on March 9, 2007, the last practicable trading day before the date of this joint proxy statement/prospectus. The calculation for the Valera proforma equivalent share price does not include CSRs.

			Valera Pro Forma
	Indevus	Valera	Equivalent
December 11, 2006	\$ 7.86	\$ 5.41	\$ 7.75
March 9, 2007	\$ 6.52	\$ 7.97	\$ 7.67

The market value of the Indevus common stock that will be issued in exchange for shares of Valera common stock upon completion of the merger will not be known at the time Valera stockholders vote to adopt the merger agreement or at the time Indevus stockholders vote to approve the issuance of Indevus common stock and CSRs in the merger.

The above tables show only historical comparisons. Because the market prices of Indevus and Valera common stock will likely fluctuate prior to completion of the merger, these comparisons may not provide

meaningful information to Indevus stockholders in determining whether to approve the issuance of Indevus common stock and CSRs in the merger and to Valera stockholders in determining whether to adopt the merger agreement. Indevus stockholders and Valera stockholders are encouraged to obtain current market quotations for shares of Indevus and Valera common stock and to review carefully the other information contained or incorporated by reference in this joint proxy statement/prospectus in considering whether to approve the applicable merger proposals. See the section entitled Where You Can Find More Information on page 257.

### **Dividend Information**

No cash dividends have ever been paid or declared on shares of Indevus or Valera common stock. Indevus does not anticipate paying cash dividends on its common stock in the near future. Any dividends paid or declared on Indevus shares will be subject to the preferential dividend of \$0.1253 per share payable on the outstanding Indevus Series B Preferred Stock (\$30,000 per annum), \$1.00 per share payable on the outstanding Indevus Series C Preferred Stock (\$5,000 per annum) and dividends payable on any other preferred stock that Indevus may issue. Indevus present intention is to retain its earnings for the future operation and expansion of its business. Any future payment of dividends on Indevus common stock will be at the discretion of its board of directors and will depend upon, among other things, Indevus earnings, financial condition, capital requirements, level of indebtedness and other factors that Indevus board of directors deems relevant.

Valera currently intends to retain future earnings, if any, to fund the development and expansion of Valera's business and does not anticipate paying cash dividends on its common stock in the foreseeable future. Under Valera's credit agreement with Merrill Lynch Capital, Valera agreed to not declare or pay any cash dividends. Any future determination to pay dividends will be at the discretion of Valera's board of directors and will depend on Valera's financial condition, results of operations, capital requirements, restrictions contained in future financing instruments and other factors Valera's board of directors deems relevant.

#### **RISK FACTORS**

In addition to the other information included or incorporated by reference in this document, you are urged to consider carefully the matters described below in determining whether to vote to approve the applicable merger proposals. Additional risks and uncertainties not presently known to us or that are not currently believed to be material, if they occur, also may adversely affect Indevus following the merger.

#### **Risks Relating to the Merger**

#### The number of shares and the value of the Indevus common stock that Valera stockholders will receive in the merger will fluctuate.

The number of shares and precise value of the merger consideration to be received by Valera stockholders at the effective time of the merger cannot be determined at the present time. The exchange ratio, which determines the number of shares of Indevus common stock that Valera stockholders will receive in the merger, will not be determined until shortly before the Valera stockholders meeting. Upon completion of the merger, each share of Valera common stock will be converted into the right to receive an amount of Indevus common stock equal to the exchange ratio. Under the terms of the merger agreement, the exchange ratio will be calculated by dividing \$7.75 by the volume weighted average, which we refer to as the Indevus Common Stock Value, of the closing prices of Indevus common stock during the 25 trading days ending on the fifth trading day prior to the date of the Valera stockholders meeting to consider the merger. The exchange ratio is subject to a collar and will range from a minimum of 0.9626 to a maximum of 1.1766 of a share of Indevus common stock, as follows:

if the Indevus Common Stock Value is \$6.59 or more but not greater than \$8.05, then the exchange ratio will be determined by dividing \$7.75 by the Indevus Common Stock Value;

if the Indevus Common Stock Value is less than \$6.59, then the exchange ratio will be 1.1766; and

if the Indevus Common Stock Value is greater than \$8.05, then the exchange ratio will be 0.9626. As a result of the collar mechanism described above, if the Indevus Common Stock Value is less than \$6.59, then the market value of the shares of Indevus common stock to be issued to Valera stockholders would have a value of less than \$7.75 per share of Valera common stock. Conversely, if the Indevus Common Stock Value is greater than \$8.05, then the market value of the shares of Indevus common stock to be issued to Valera stockholders would have a value of Valera common stock to be issued to Valera stockholders would have a value of greater than \$7.75 per share of Valera common stock to be

The price of Indevus common stock at the closing of the merger may vary from its price on the date the merger agreement was executed, on the date of this joint proxy statement/prospectus and on the date of the Valera stockholders meeting. Stock price changes may result from a variety of factors beyond Indevus control, including general economic and market conditions. Because the date that the merger is completed may be later than the date of the Valera stockholders meeting, at the time of the Valera stockholders meeting, Valera stockholders will not know the exact market value of the Indevus common stock that Valera stockholders will receive upon completion of the merger. In addition, there will be a period of time between completion of the merger and the time at which former Valera stockholders may not be able to sell their Indevus shares in the open market and, therefore, may not be able to avoid losses from any decrease in the trading price of Indevus common stock during that period.

#### If the applicable milestones are not achieved, the contingent stock rights will not convert into Indevus common stock.

In the merger, each share of Valera common stock will also convert into three contingent stock rights, or CSRs. Each CSR relates to one of three Valera product candidates Supprelin-LA, the ureteral stent and

VP003 (Octreotide implant). The CSRs become convertible into \$1.00, \$1.00 and \$1.50, respectively, worth of Indevus common stock only if the milestone or milestones applicable to that product approval by the U.S. Food and Drug Administration, or FDA, and, in the case of Supprelin-LA, Indevus possession of a specified amount of inventory of commercially saleable units are achieved on a timely basis. If the applicable milestone or milestones are not achieved within three years of completing the merger in the case of Supprelin-LA and within five years of completing the merger in the case of the ureteral stent and VP003 (Octreotide implant), the respective CSRs will expire and no additional shares of Indevus common stock will be issued in connection with those CSRs.

The milestones may not be achieved in a timely manner, or at all, due to numerous factors including delays in the FDA approval process. In addition, Indevus is obligated to use only commercially reasonable efforts to develop these products. Under the terms of the merger agreement, in this context, commercially reasonable efforts means those efforts and resources normally used by Indevus to develop a product it owns or to which it has exclusive rights, which is of similar market potential at a similar stage in its development or product life, taking into account issues of safety and efficacy, product profile, competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory and reimbursement structure involved, the profitability of the applicable products and other relevant factors.

# Holders of the CSRs may not receive the full number of shares of Indevus common stock that would otherwise be issuable upon conversion of the CSRs.

The aggregate number of shares of Indevus common stock that may be issued in the event one or more CSRs become convertible into Indevus common stock is limited and may not exceed the number of shares of Indevus common stock issued as part of the merger consideration upon completion of the merger. This may result in holders of CSRs not receiving the full number of shares of Indevus common stock that would otherwise be issuable upon conversion of CSRs.

#### Indevus may be unable to integrate successfully the businesses of Valera and realize the anticipated benefits of the merger.

The success of the merger will depend, in part, on Indevus ability to realize the anticipated synergies, growth opportunities and cost savings from integrating Valera's business with Indevus business. Indevus success in realizing these benefits and the timing of this realization depend upon the successful integration of the operations of Valera. The integration of two independent companies is a complex, costly and time-consuming process. The difficulties of combining the operations of the companies include, among other factors:

coordinating geographically separated organizations, systems and facilities, including complexities associated with managing the combined businesses at two separate locations;

combining the sales force territories and competencies associated with the sale of products presently sold by Indevus or Valera;

integrating personnel from different companies while maintaining focus on providing consistent, high-quality products and customer service;

unforeseen expenses or delays associated with the merger; and

performance shortfalls at one or both of the companies as a result of the diversion of management s attention to the merger. If we are unable to combine successfully the businesses of Indevus and Valera in a manner that permits the combined company to achieve the cost savings and operating synergies anticipated to result from the merger, such anticipated benefits of the merger may not be realized fully or at all or may take longer to realize than expected. In addition, Indevus and Valera have operated and, until the completion of the merger, will continue to

operate, independently. It is possible that the integration process could result in the loss of key employees, diversion of each company s management s attention, the disruption or interruption of, or the loss of momentum in, each company s ongoing business or inconsistencies in standards, controls, procedures and policies, any of which could adversely affect our ability to maintain relationships with customers, suppliers and employees or our ability to achieve the anticipated benefits of the merger, or could reduce our earnings or otherwise adversely affect the business and financial results of the combined company.

#### Employee uncertainty related to the merger could harm the combined company.

Current and prospective Indevus and Valera employees may experience uncertainty about their future as employees of the combined company until strategies with regard to Valera are announced or executed. This may adversely affect Indevus and Valera's ability to attract and retain, and may affect the performance during the transition period of, key management, sales, marketing and technical personnel.

# The merger is subject to conditions to closing that could result in the merger being delayed or not consummated, which could negatively impact Indevus or Valera s stock price and future business and operations.

The merger is subject to conditions to closing as set forth in the merger agreement, including obtaining the requisite Indevus and Valera stockholder approvals. If any of the conditions to the merger are not satisfied or, where permissible, not waived, the merger will not be consummated. Failure to consummate the merger could negatively impact Indevus or Valera's stock price, future business and operations, and financial condition. Any delay in the consummation of the merger or any uncertainty about the consummation of the merger may adversely affect the future businesses, growth, revenue and results of operations of either or both of the companies or the combined company.

# Failure to complete the merger could negatively impact the market price of Indevus common stock and/or Valera common stock and the future business and financial results of Indevus and Valera.

If the merger is not completed for any reason, the ongoing businesses of Indevus and Valera may be adversely affected and will be subject to a number of risks, including:

Valera or Indevus might have to pay the other a termination fee of \$5.0 million, or Indevus or Valera might be required to reimburse the other for up to \$3.0 million of expenses relating to the merger;

failure to pursue other beneficial opportunities as a result of the focus of management of each of the companies on the merger, without realizing any of the anticipated benefits of completing the merger;

the market price of Indevus common stock or Valera common stock might decline to the extent that the current market price reflects a market assumption that the merger will be completed; and

Indevus and Valera's unreimbursed costs incurred related to the merger must be paid even if the merger is not completed. If the merger agreement is terminated and Valera's board of directors seeks another merger or business combination, Valera stockholders cannot be certain that Valera will be able to find a party willing to pay an equivalent or more attractive price than the price Indevus has agreed to pay in the merger.

# In the event Indevus does not effectively manage its expanded sales force, marketing and sales of Vantas, or development of Supprelin-LA, the ureteral stent, VP003 (Octreotide implant) or other products in development, operating results may be materially adversely affected.

As a result of the merger, Indevus will be increasing the size of its specialty sales force, adding Valera s Vantas to the products it currently sells and adding Supprelin-LA, the ureteral stent, VP003 (Octreotide implant), and other Valera product candidates in development, to its development pipeline. Immediately following the

merger, the expanded Indevus specialty sales force might be unable to successfully market and sell Vantas, or the resources devoted to incorporating Vantas could cause the combined company to less effectively market and sell existing Indevus products. In addition, Indevus development team might not be able to obtain approval for Supprelin-LA, the ureteral stent, VP003 (Octreotide implant), and the other Valera products in development. If Indevus is unable to successfully market and sell Vantas or obtain FDA approval for Supprelin-LA, the ureteral stent, VP003 (Octreotide implant), and the other Valera product candidates in development, it may have a material adverse effect on the combined company after the merger and, as a result, on the market price of Indevus common stock.

#### If Indevus is unable to retain key Indevus or Valera personnel after the merger is completed, Indevus business may suffer.

The success of the merger will depend in part on Indevus ability to retain sales, marketing, development, manufacturing and other personnel currently employed by Indevus and those key Valera employees who continue employment with Indevus after the merger. It is possible that these employees might decide not to remain with Indevus after the merger is completed. If key employees terminate their employment, or insufficient numbers of employees are retained to maintain effective operations, the combined company s sales, marketing or development activities might be adversely affected, management s attention might be diverted from successfully integrating Valera s operations to hiring suitable replacements, and the combined company s business might suffer. In addition, Indevus might not be able to locate suitable replacements for any key employees that leave Indevus or offer employment to potential replacements on reasonable terms.

# Charges to earnings resulting from the application of the purchase method of accounting might adversely affect the market value of Indevus common stock following the merger.

In accordance with U.S. GAAP, the merger will be accounted for using the purchase method of accounting, which will result in charges to earnings that could have an adverse impact on the market value of Indevus common stock following completion of the merger. Under the purchase method of accounting, the total estimated purchase price will be allocated to Valera s net tangible assets, identifiable intangible assets or expense for research and development based on their fair values as of the date of completion of the merger. Any excess of the purchase price over those fair values will be recorded as goodwill. The combined company will incur additional amortization expense based on the identifiable amortizable intangible assets acquired pursuant to the merger agreement and their relative useful lives. Additionally, to the extent the value of goodwill or identifiable intangible assets or other long-lived assets become impaired, the combined company will be required to incur material charges relating to the impairment. These amortization and potential impairment charges could have a material impact on the combined company s results of operations.

Indevus currently estimates that it will incur approximately \$2.0 million of incremental annual amortization expense after completion of the merger. Changes in earnings per share, including as a result of this incremental expense, could adversely affect the trading price of Indevus common stock.

#### Indevus and Valera will incur substantial expenses whether or not the merger is completed.

Indevus and Valera will incur substantial expenses related to the merger whether or not the merger is completed. Indevus currently expects to incur approximately \$4.5 million in transactional expenses, approximately \$2.9 million of which are not contingent on the completion of the merger. Valera currently expects to incur approximately \$3.8 million in transactional expenses, approximately \$2.1 of which are not contingent on the completion of the merger. Moreover, in the event the merger agreement is terminated, Valera or Indevus may, under certain circumstances, be required to pay the other a \$5.0 million termination fee or reimburse out-of-pocket expenses of up to \$3.0 million. Also, should the merger agreement be terminated due to a willful breach of the merger agreement by one of the parties, such party could owe significant damages to the other. See the section entitled The Merger Agreement Termination Fees; Reimbursement of Expenses on page 128.

# In the event the merger is completed, Indevus will incur significant additional expenses in connection with the integration of the two businesses

In the event the merger is completed, Indevus expects to incur significant additional expenses in connection with the integration of the two businesses, including integrating personnel, geographically diverse operations, information technology systems, accounting systems, customers, and strategic partners of each company and implementing consistent standards, policies, and procedures, and may be subject to possibly material write downs in assets and charges to earnings, which are expected to include severance pay and other costs.

# The pro forma financial statements are presented for illustrative purposes only and may not be an indication of the combined company s financial condition or results of operations following the merger

The pro forma financial statements contained in this joint proxy statement/prospectus are presented for illustrative purposes only and may not be an indication of the combined company s financial condition or results of operations following the merger for several reasons. For example, the pro forma financial statements have been derived from the historical financial statements of Indevus and Valera and certain adjustments and assumptions have been made regarding the combined company after giving effect to the merger. The information upon which these adjustments and assumptions have been made is preliminary, and these kinds of adjustments and assumptions are difficult to make with complete accuracy. Moreover, the pro forma financial statements do not reflect all costs that are expected to be incurred by the combined company in connection with the merger. For example, the impact of any incremental costs incurred in integrating the two companies is not reflected in the pro forma financial statements. As a result, the actual financial condition and results of operations of the combined company following the merger may not be consistent with, or evident from, these pro forma financial statements.

In addition, the assumptions used in preparing the pro forma financial information may not prove to be accurate, and other factors may affect the combined company s financial condition or results of operations following the merger. Any potential decline in the combined company s financial condition or results of operations may cause significant variations in the stock price of the combined company. See the section entitled Unaudited Pro Forma Combined Consolidated Financial Information beginning on page 25.

# Some of the executive officers and directors of Valera have conflicts of interest or additional interests that might have influenced them to support and approve the merger.

Valera s executive officers and directors might have been influenced to support and approve the merger because of arrangements that provide them with interests in the merger that are different from, or in addition to, the interests of Valera stockholders in the merger, which are described under the section entitled The Merger Additional Interests of Valera Directors and Executive Officers in the Merger on page 99, including the following

severance and other payments and benefits to certain executive officers of Valera pursuant to existing change in control and employment agreements with Valera and a consulting arrangement between Dr. David S. Tierney, Valera s President and Chief Executive Officer, and Indevus during a transition period after the completion of the merger;

share issuances to Valera executive officers and directors in consideration of the cancellation of all options to purchase Valera common stock in connection with the merger;

employment agreements expected to be entered into between Indevus and certain officers of Valera, and, in the case of James C. Gale, Valera s chairman of the board, an expected membership on Indevus board of directors;

rights to continued director and executive officer indemnification and insurance coverage by Indevus after the merger for acts or omissions occurring before the merger;

registration rights covering the shares of Indevus common stock acquired by SMH (and affiliated entities; James C. Gale, Valera s chairman of the board, is the chief investment officer of those SMH affiliated entities) in connection with the merger for resale under

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the Securities Act on a Registration

Statement on Form S-3 to be filed by Indevus within 30 days following the effective time of the merger; and

severance payments to another executive officer of Valera pursuant to the Severance Pay Plan established by Indevus in connection with the merger.

# If Valera's former stockholders immediately sell Indevus common stock received in the merger, they could cause Indevus common stock price to decline.

The Indevus common stock to be issued in the merger will be registered under the federal securities laws. As a result, those shares will be immediately available for resale in the public market, except for shares of Indevus common stock that will be subject to additional transfer restrictions because those shares were issued to Valera s former stockholders who were affiliates of Valera before the merger or who become affiliates of Indevus after the merger. See the section entitled The Merger Resale of Indevus Common Stock Issued in Connection with the Merger; Affiliate Agreements on page 111. The number of shares of Indevus common stock to be issued to Valera s former stockholders in connection with the merger, and immediately available for resale, will equal approximately 21% to 25% of the number of outstanding Indevus common shares. Valera s former stockholders may sell the stock they receive immediately after the merger. If this occurs, or if other holders of Indevus stock sell significant amounts of Indevus common stock immediately after the merger is completed, the market price of Indevus common stock could decline. These sales may also make it more difficult for Indevus to sell equity securities in the future at a time and at a price that Indevus deems appropriate to raise funds through future offerings of common stock.

In addition, Indevus has agreed to register the shares of Indevus common stock acquired by Sanders Morris Harris, Inc. (and affiliated entities), or SMH, in connection with the merger for resale under the Securities Act on a Registration Statement on Form S-3 to be filed by Indevus within 30 days following the effective time of the merger. The number of shares to be issued to SMH will equal approximately 7.7% to 9.1% of outstanding Indevus common stock. If SMH sells significant amounts of Indevus common stock immediately after the resale registration statement is effective, the market price for Indevus common stock could decline and it may make it more difficult for Indevus to sell equity securities at a time and at a price Indevus deems appropriate to raise funds through future offerings of common stock.

# The market price of the Indevus common stock after the merger might be affected by factors different from those affecting the shares of Valera or Indevus currently.

The businesses of Indevus and Valera differ somewhat and, accordingly, the results of operations of the combined company and the market price of the combined company s common stock might be affected by factors different from those currently affecting the independent results of operations of each of Indevus or Valera. For a discussion of the businesses of Indevus and Valera and of factors to consider in connection with those businesses, see the documents incorporated by reference in this document and referred to under the section entitled Where You Can Find More Information beginning on page 257, the Risks Relating to Valera described below and the section entitled Information about Valera beginning on page 139.

#### The merger agreement limits Valera s ability to pursue alternative business combinations.

Certain no shop provisions included in the merger agreement make it difficult for Valera to sell its business to a party other than Indevus. These provisions include the general prohibition on Valera soliciting any acquisition proposal or offer for a competing transaction, a requirement that Valera pay a termination fee of \$5.0 million if the merger agreement is terminated in specified circumstances and a requirement that Valera reimburse Indevus fees and expenses of up to \$3.0 million if the merger agreement is terminated in specified circumstances. See The Merger Agreement No Solicitation by Valera beginning on page 121 of this joint proxy statement/prospectus, The Merger Agreement Termination of the Merger Agreement beginning on page 127, and The Merger Agreement Termination Fees; Reimbursement of Expenses beginning on

page 128. These provisions might discourage a third party with an interest in acquiring all of or a significant part of Valera from considering or proposing an acquisition, including a proposal that might be more advantageous to the stockholders of Valera when compared to the terms and conditions of the merger described in this joint proxy statement/prospectus. Furthermore, the termination fee may result in a potential competing acquirer proposing to pay a lower per share price to acquire Valera than it might otherwise have proposed to pay to Valera stockholders.

#### The merger may be completed even though Indevus or Valera suffers a material adverse effect on its business.

In general, either Indevus or Valera may refuse to complete the merger if the other party suffers a material adverse effect on its business between December 11, 2006, the date of the signing of the merger agreement, and the date the merger would otherwise close. However, the parties have agreed that the following changes or occurrences would be deemed to not constitute a material adverse effect:

any change relating to the economy or securities markets in general;

any adverse change, effect, event, occurrence, state of facts or development attributable to conditions affecting the industry in which Indevus or Valera, as applicable, participates, including any changes to reimbursement rates related to any Valera products, so long as the effects of any of the foregoing do not disproportionately impact Indevus or Valera, as applicable;

any decline in Indevus or Valera s net sales after the date of the merger agreement;

any failure, in and of itself, by Indevus or Valera to meet any internal or published projections, forecasts or revenue or earnings predictions for any period ending on or after the date of the merger agreement;

the effect of any change in any applicable law or GAAP; or

any events or occurrences directly or indirectly related to the impact of the merger agreement (or the merger) or the announcement or performance of the merger agreement (or the merger) or the transactions contemplated by the merger agreement (or the merger). In addition, the parties have agreed that Valera s receipt of a nonapprovable letter with regard to Supprelin-LA, taken alone, will not constitute a material adverse effect on Valera.

In addition, either Indevus or Valera could waive the closing condition related to the occurrence of a material adverse effect on the other party and the merger would be completed even if a material adverse effect had occurred.

#### Indevus Will Need to Raise Additional Financing Following the Merger

Indevus believes that its existing cash resources will be sufficient to fund its planned combined operations through November 2007. There are certain events that could add significant additional cash resources to fund the operations of the combined company. Among these events, Indevus may receive, upon FDA approval of SANCTURA XR, a payment of approximately \$35,000,000 from Esprit, payable at Esprit s option, which would add to Indevus cash resources. FDA approval may occur as early as August 2007, although there can be no assurance that FDA approval can be obtained. If Indevus does not receive the \$35,000,000 payment from Esprit, Indevus would need to obtain additional funding prior to November 2007 through corporate collaborations, strategic combinations or public or private equity or debt financing or a combination of such alternatives. In the event the stockholders of Indevus do not approve the proposed amendment to increase the number of authorized shares of common stock under the Indevus Restated Certificate of Incorporation, Indevus may not have sufficient shares of common stock to consummate equity based financing following the merger and would have to rely on the other alternatives discussed above. Although Indevus believes it will receive the \$35,000,000 payment if the FDA approves the SANCTURA XR NDA, or would otherwise be able to obtain additional capital to fund its operations, there can be no assurance that the \$35,000,000 payment from Esprit will be received or that

additional capital can be obtained on favorable terms or at all. The failure to receive such payment or raise such funds would result in Indevus significantly curtailing its marketing and operations and delay development efforts, which would have a material adverse effect on Indevus.

#### **Risks Relating to Indevus**

#### Risks Related to Indevus Business

#### Indevus is dependent on SANCTURA.

Indevus derives a substantial portion of its revenue from Esprit, its marketing partner, under Indevus agreement with Esprit relating to SANCTURA, or the SANCTURA Agreement. Indevus believes that revenues derived under the SANCTURA Agreement will continue to account for a substantial portion of Indevus revenue for the foreseeable future. Indevus is highly dependent on Esprit for the commercialization and marketing of SANCTURA and for performance of its obligations under the SANCTURA Agreement. The failure of Esprit to perform its obligations under this agreement, or to market SANCTURA, could adversely affect Indevus business, financial condition and results of operations. In particular, if sales of SANCTURA do not increase, Indevus is unlikely to derive royalties in excess of the minimum royalties under the SANCTURA Agreement and, after the minimum royalty period expires in June 2008, Indevus royalty revenue may decrease substantially. Esprit is not obligated to purchase any minimum amount of SANCTURA from Indevus. SANCTURA may suffer from generic penetration after the expiration of the market exclusivity period in May 2009, and competes with many once-daily and other formulations of products to treat overactive bladder. Indevus long-term success will be highly dependent on its ability to successfully develop, manufacture and commercialize SANCTURA XR. If SANCTURA does not continue to achieve market acceptance or if Esprit provides notice to Indevus that it does not intend to pay Indevus the development milestone related to FDA approval of SANCTURA XR causing the rights to SANCTURA XR are unsuccessful, Indevus business, financial condition and results of operations may be materially adversely affected. Further, Indevus sales force subsidy for its co-promotion of SANCTURA XR in the U.S. expires on December 31, 2008.

Because Indevus marketing resources are limited, it may be unable to devote sufficient resources to SANCTURA to achieve increasing market acceptance of SANCTURA in the highly competitive marketplace for overactive bladder therapies. Indevus failure to expend the resources to adequately promote SANCTURA would have a material adverse effect on its business and results of operations.

Moreover, because Indevus has fewer sales representatives than its competitors, its sales force may be unable to detail successfully to physicians who prescribe overactive bladder medications. Indevus may not be able to retain all of its current sales representatives. Even if Indevus hires additional representatives, they may not be effective in promoting the sale of SANCTURA. The failure of its sales representatives to be successful in selling SANCTURA would have a material adverse effect on operating results.

#### Indevus may not compete successfully in the overactive bladder market.

Competition in the overactive bladder market is intense and has increased since the launch of SANCTURA in August 2004 and two other competitive products in early 2005. SANCTURA may not compete successfully with current drug therapies for overactive bladder or with new drugs which may reach the market in the future. SANCTURA competes with drugs and other therapies for overactive bladder marketed by many large, multinational companies who have substantially greater marketing and financial resources and experience than Indevus. In addition, antimuscarinics and antispasmodics for overactive bladder are the subject of testing or commercialization efforts by other companies, including certain treatments for which approval may be sought in the future. Launches of other competitive products may occur in the near future and Indevus cannot predict with accuracy the timing or impact of the introduction of competitive products or their possible effect on Indevus sales.

Indevus license for SANCTURA does not include any patents that it expects to use in commercializing the product for overactive bladder. Indevus ability to successfully commercialize SANCTURA in the U.S. will depend on the continued availability of market exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Waxman-Hatch Act, which provides protections for certain new products. The Waxman-Hatch Act provides for a period of market exclusivity in the U.S. for SANCTURA for five years from the date of FDA approval, May 28, 2004. The marketing of SANCTURA could be materially adversely affected if the period of market exclusivity is shortened. After this time, there may be generic versions of trospium chloride available to treat overactive bladder at significantly lower prices than SANCTURA, in which case sales of SANCTURA will likely decrease significantly. Indevus cannot predict whether any patents will issue on the applications that have been filed for SANCTURA XR, an extended release, once-daily formulation of SANCTURA. If granted, there can be no assurance that these patents can or will preclude eventual market erosion from new technologies or competing products. If Indevus is unable to obtain a patent on such formulation it will have to rely solely on market exclusivity for this formulation, which will be shorter than five years.

#### Indevus product candidates including SANCTURA XR and NEBIDO may not be successfully developed or achieve market acceptance.

Indevus currently has six compounds which are in various stages of development and have not been approved by the FDA, including SANCTURA XR and NEBIDO. These product candidates are subject to the risk that any or all of them are found to be ineffective or unsafe, or otherwise may fail to receive necessary regulatory clearances. Indevus is unable to predict whether any of these product candidates will receive regulatory clearances or will be successfully manufactured or marketed. Further, due to the extended testing and regulatory review process required before marketing clearance can be obtained, the time frames for commercialization of any products are long and uncertain. Even if these product candidates receive regulatory clearance, Indevus products may not achieve or maintain market acceptance.

#### Indevus relies on the favorable outcome of clinical trials of its product candidates including SANCTURA XR and NEBIDO.

Before obtaining regulatory approval for the commercial sale of any of the pharmaceutical products Indevus is developing, it or its licensees must demonstrate that the product is safe and efficacious for use in each target indication. The process of obtaining FDA and other regulatory approvals is lengthy and expensive. If clinical trials do not demonstrate the safety and efficacy of certain products under development, Indevus will be materially adversely affected. The results of pre-clinical studies and early clinical trials may not predict results that will be obtained in large-scale testing or use. Clinical trials of products Indevus is developing may not demonstrate the safety and efficacy of such products. Regardless of clinical trial results, the FDA may not approve marketing of the product. The costs to obtain regulatory approvals are considerable and the failure to obtain, or delays in obtaining, regulatory approval could have a significant negative effect on Indevus business performance and financial results. Even if pre-launch approval of a product is obtained, the FDA is authorized to impose post-marketing requirements. A number of companies in the pharmaceutical industry, including Indevus, have suffered significant setbacks in advanced clinical trials of pagoclone that demonstrate statistically significant efficacy, two in panic disorder and one in GAD, other trials have failed to demonstrate statistically significant efficacy, prompting Pfizer (Indevus previous licensee of this compound) to elect not to pursue further development of the compound and to return to Indevus all rights to pagoclone.

#### Indevus has regulatory and guideline risks.

On May 28, 2004, the FDA approved SANCTURA. The FDA may impose post-marketing or other regulatory requirements after approval, which could have an adverse affect on the commercialization of SANCTURA. In addition, although SANCTURA have thus far demonstrated an acceptable safety profile in clinical trials, there can be no assurance that the safety profile of the drug would not change when assessed in future trials or when used by a larger patient population.

If SANCTURA becomes subject to efficacy or safety concerns, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales, unexpected side effects or regulatory proceedings, the impact on Indevus revenues could be significant.

Government health care cost-containment measures can significantly affect Indevus sales and profitability. These include federal, state, and foreign laws and regulations that negatively affect pharmaceutical pricing, such as Medicaid and Medicare; pharmaceutical importation laws, and other laws and regulations that, directly or indirectly, impose governmental controls on the prices at which SANCTURA is sold.

Government agencies promulgate regulations and guidelines directly applicable to Indevus and SANCTURA. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of SANCTURA or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of SANCTURA.

Acceptable levels of reimbursement for costs of developing and manufacturing of pharmaceutical products and treatments related to those pharmaceutical products by government authorities, private health insurers and other organizations, such as HMOs, will have an effect on the successful commercialization of, and attracting collaborative partners to invest in the development of, Indevus products and product candidates. Indevus cannot be sure that reimbursement in the United States or elsewhere will be available for any pharmaceutical products it may develop or, if already available, will not be decreased in the future. The U.S. Congress recently enacted a limited prescription drug benefit for Medicare recipients in the Medicare Prescription Drug and Modernization Act of 2003. While the program established by this statute may increase demand for Indevus products, if it participates in this program, its prices will be negotiated with drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries. Also, Indevus cannot be sure that reimbursement is not available or is available only at limited levels, it may not be able to obtain collaborative partners to manufacture and commercialize its products, and may not be able to obtain a satisfactory financial return on its own manufacture and commercialization of any future products.

Third-party payors are increasingly challenging prices charged for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for pharmaceutical products, including any products that may be offered by Indevus in the future. Cost-cutting measures that health care providers are instituting, and the effect of any health care reform, could materially adversely affect Indevus ability to sell any products that it successfully develops and approved by regulators. Moreover, it is unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on Indevus business.

#### Indevus is dependent on third parties to manufacture SANCTURA and SANCTURA XR.

Indevus is currently dependent on Madaus to manufacture SANCTURA and will be dependent on a third party for the manufacture of SANCTURA XR. Indevus is also dependent on third parties in the supply chain, for the manufacture of trospium chloride, the active pharmaceutical ingredient in SANCTURA and SANCTURA XR. If Madaus or any of the other third parties were unable to maintain compliance with FDA requirements for manufacturers of drugs sold in the U.S., Indevus would need to seek alternative sources of supply, which could create disruptions in the supply of SANCTURA or SANCTURA XR.

#### Indevus relies on third parties to commercialize and manufacture its products.

Indevus has limited sales and marketing capabilities to market its products. Substantial additional funds will be required to complete development and commercialization of its products and, accordingly, Indevus expects to seek corporate partnerships for the manufacture and commercialization of its products. Indevus may not be successful in finding corporate partners and the terms of any such arrangements may not be favorable to it or its security holders. If Indevus is unable to obtain any such corporate partners, development of its product candidates could be delayed or curtailed, which could materially adversely affect its operations and financial condition.

Any collaborative partners may not be successful in commercializing Indevus products or may terminate their collaborative agreements with Indevus. If Indevus enters into any collaborative arrangements, it will depend on the efforts of these collaborative partners and it will have limited or no control over the development, manufacture and commercialization of the products subject to the collaboration. If certain of its collaborative partners terminate the related agreements or fail to develop, manufacture or commercialize products, Indevus would be materially adversely affected. Because Indevus expects generally to retain a royalty interest in sales of products licensed to third parties, its revenues may be less than if it marketed products directly.

Indevus currently contracts with third parties for all of its manufacturing needs and does not manufacture any of its own products or product candidates. In order to continue to develop products, apply for regulatory approvals and commercialize products, Indevus will need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities. Certain of Indevus requirements for supplies or clinical compounds are filled by purchase orders on an as-requested basis and are not the subject of long-term contracts. As a result, it cannot be certain that manufacturing sources will continue to be available or that it can continue to outsource the manufacturing of these products or product candidates on reasonable terms or at all.

Any manufacturing facilities for any of Indevus compounds are subject to FDA inspection both before and after NDA approval to determine compliance with current good manufacturing practices, or cGMP, requirements. There are a limited number of contract manufacturers that operate under cGMP that are capable of manufacturing its products. If Indevus is unable to arrange for third-party manufacturing of its products, or to do so on commercially reasonable terms, Indevus may not be able to complete development of Indevus products or commercialize them. Facilities used to produce its compounds may not have complied, or may not be able to maintain compliance, with cGMP. The cGMP regulations are complex and failure to be in compliance could lead to non-approval or delayed approval of an NDA which would delay product launch or, if approval is obtained, may result in remedial action, penalties and delays in production of material acceptable to the FDA. Currently, Schering s NEBIDO manufacturing facilities have not been approved by the FDA.

Reliance on third-party manufacturers entails risks to which Indevus would not be subject if it manufactured all of its products itself, including reliance on the third party for regulatory compliance, the possibility of breach of the manufacturing agreement by the third party and the possibility of termination or non-renewal of the agreement by the third party, at a time that is costly or inconvenient for Indevus.

#### Indevus failure to acquire and develop additional product candidates will impair its ability to grow.

Indevus does not conduct its own research to discover new drug compounds. Instead, it depends on the acquisition of compounds from others for development through licensing, partnerships, corporate collaborations, strategic corporate transactions or company acquisitions. Therefore, in order to grow, Indevus must continue to acquire and develop additional compounds. The success of this strategy depends upon its ability to identify, select and acquire compounds that meet the criteria it has established. Identifying suitable compounds is a lengthy, complex and uncertain process. In addition, Indevus competes with other companies with substantially greater financial, marketing and sales resources, for the acquisition of compounds. Indevus may not be able to acquire the rights to additional compounds through licensing or strategic acquisitions of selected assets or businesses, on terms it finds acceptable or at all.

# Indevus may undertake strategic acquisitions in the future and any difficulties from integrating such acquisitions could adversely affect its stock price, operating results and results of operations.

Indevus may acquire companies, businesses and products that complement or augment its existing business. Indevus may not be able to integrate any acquired business or product successfully or operate any acquired business profitably. Integrating any newly acquired business or product could be expensive and time-consuming. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational and financial resources and could prove to be more difficult or expensive than Indevus predicts. The diversion of its management s attention and any delay or difficulties encountered in connection with any future acquisitions it may consummate could result in the disruption of its on-going business or inconsistencies in standards, controls, procedures and policies that could negatively affect its ability to maintain relationships with customers, suppliers, collaborators, employees and others with whom it has business dealings. Moreover, Indevus may need to raise additional funds through public or private debt or equity financing to acquire any businesses or products, which may result in dilution for stockholders or the incurrence of indebtedness.

As part of Indevus efforts to acquire companies, businesses or product candidates or to enter into other significant transactions, it conducts business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite its efforts, it ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction. If Indevus fails to realize the expected benefits from acquisitions it may consummate in the future, whether as a result of unidentified risks, integration difficulties, regulatory setbacks and other events, Indevus business, results of operations and financial condition could be adversely affected. If it acquires product candidates, it will also need to make certain assumptions about, among other things, development costs, the likelihood of receiving regulatory approval and the market for such product candidates. Indevus assumptions may prove to be incorrect, which could cause it to fail to realize the anticipated benefits of these transactions.

In addition, it will likely experience significant charges to earnings in connection with its efforts, if any, to consummate acquisitions. For transactions that are ultimately not consummated, these charges may include fees and expenses for investment bankers, attorneys, accountants and other advisors in connection with its efforts. Even if Indevus efforts are successful, it may incur, as part of a transaction, substantial charges for closure costs associated with elimination of duplicate operations and facilities and acquired in-process research and development charges. In either case, the incurrence of these charges could adversely affect its results of operations for particular quarterly or annual periods.

#### Indevus needs additional funds in the future.

Indevus existing cash resources will be insufficient to commercialize any of its current product candidates on its own. In addition, it continues to expend substantial funds for research and development, marketing, general and administrative expenses and manufacturing. Indevus expects to continue to use substantial cash for operating activities in fiscal 2007 as it continues to fund its development activities, as well as marketing activities related to SANCTURA and DELATESTRYL. Indevus may seek additional funding through corporate collaborations, strategic combinations or public or private equity and debt financing options. Any such corporate collaboration, strategic combination or financial transactions could result in material changes to the capitalization, operations, management and prospects for its business and no assurance can be given that the terms of a strategic transaction would be favorable to Indevus or its security holders. If Indevus raises additional funds by issuing equity securities, existing stockholders will be diluted and future investors may be granted rights superior to those of existing stockholders. There can be no assurance that additional financing will be available on terms acceptable to Indevus or at all. If Indevus sells securities in a private offering, it may have to sell such shares at a discount from the market price of its stock which could have a depressive effect on its stock price. In addition, future resales of shares in the public market sold in a private offering could negatively affect its stock price.



Indevus cash requirements and cash resources will vary significantly depending upon the following principal factors:

marketing success of SANCTURA;

marketing success of DELATESTRYL, sales of which may be negatively impacted if NEBIDO is introduced to the market;

the costs and progress of its research and development programs;

the timing and cost of obtaining regulatory approvals; and

whether it is successful in either in-licensing or out-licensing products.

As a result of the uncertainties and costs associated with business development activities, market conditions and other factors generally affecting Indevus ability to raise additional funds, it may not be able to obtain sufficient additional funds to satisfy cash requirements in the future or may be required to obtain financing on terms that are not favorable to it. Indevus may have to curtail its operations or delay development of its products.

#### Indevus has a history of losses and expect losses to continue.

Indevus has incurred substantial net losses over the past five fiscal years including net losses of approximately \$17,600,000, \$31,800,000, \$68,200,000, \$53,200,000 and \$50,600,000 for fiscal years 2002, 2003, 2004, 2005, and 2006, respectively. At December 31, 2006 it had an accumulated deficit of approximately \$483,000,000.

Indevus continues to experience losses and to use substantial amounts of cash in operating activities. Indevus will be required to conduct significant development and clinical testing activities for the products it is developing and these activities are expected to result in continued operating losses and use of cash for the foreseeable future. It cannot predict the extent of future losses or the time required to achieve profitability.

#### Indevus may not be profitable in the future.

Indevus may never achieve or sustain profitability in the future. Indevus expects to continue to experience fluctuations in revenue as a result of the timing of regulatory filings or approvals, product launches, license fees, royalties, product shipments, and milestone payments. Indevus also continues to expect fluctuations in expense from the timing of clinical trials, payments to licensors for development milestones, and in licensing fees for new product candidates.

#### The outcome of the Redux litigation could materially harm Indevus.

On September 15, 1997, Indevus announced a market withdrawal of its first commercial prescription product, the weight loss medication Redux, which had been launched by AHP, now Wyeth, Indevus licensee, in June 1996. Following the withdrawal, Indevus has been named, together with other pharmaceutical companies, as a defendant in several thousand product liability legal actions, some of which purport to be class actions, in federal and state courts relating to the use of Redux and other weight loss drugs. The existence of such litigation may materially adversely affect Indevus business. In addition, although Indevus is unable to predict the outcome of any such litigation, if successful uninsured or insufficiently insured claims, or if a successful indemnification claim, were made against it, its business, financial condition and results of operations could be materially adversely affected. In addition, the uncertainties associated with these legal actions have had, and may continue to have, an adverse effect on the market price of its common stock and on its ability to obtain corporate collaborations or additional financing to satisfy cash requirements, to retain and attract qualified personnel, to develop and commercialize products on a timely and adequate basis, to acquire rights to additional products, and to obtain product liability insurance for other products at costs acceptable to Indevus, or at all, any or all of which may materially adversely affect its business, financial condition and results of operations.

On May 30, 2001, Indevus entered into the Indemnity and Release Agreement with AHP, now Wyeth, which provides for indemnification of Redux-related claims brought by plaintiffs who initially elected not to stay in the AHP national class action settlement of diet drug litigation and by those claimants who allege primary pulmonary hypertension, a serious disease involving the blood vessels in the lungs. This agreement also provides for funding of all defense costs related to all Redux-related claims and provides for Wyeth to fund certain additional insurance coverage to supplement Indevus existing product liability insurance. However, there can be no assurance that uninsured or insufficiently insured Redux-related claims or Redux-related claims for which Indevus is not otherwise indemnified or covered under the AHP indemnity and release agreement will not have a material adverse effect on its future business, results of operations or financial condition or that the potential of any such claims would not adversely affect its ability to obtain sufficient financing to fund operations. Indevus is unable to predict whether the existence of such litigation may adversely affect its business.

Pursuant to agreements Indevus has with Les Laboratories Servier, from whom it in-licensed rights to Redux, Boehringer Ingelheim Pharmaceuticals, Inc., the manufacturer of Redux, and other parties, it may be required to indemnify such parties for Redux-related liabilities. Indevus is unable to predict whether such indemnification obligations, if they arise, may adversely affect its business.

#### Indevus relies on the protection provided by its intellectual property and has limited patent protection on some of its products.

Its future success will depend to a significant extent on its ability to:

obtain and enforce patent protection on Indevus products and technologies;

maintain trade secrets; and

operate and commercialize products without infringing on the patents or proprietary rights of others.

There can be no assurance that patent applications filed by Indevus or others, in which it has an interest as assignee, licensee or prospective licensee, will result in patents being granted or that, if granted, any of such patents will afford protection against competitors with similar technology or products, or could not be circumvented or challenged. In addition, certain products Indevus is developing or selling are not covered by any patents and, accordingly, it will be dependent on obtaining market exclusively under the Waxman-Hatch Act for such products. If Indevus is unable to obtain strong proprietary rights protection of its products after obtaining regulatory clearance, competitors may be able to market competing generic products by obtaining regulatory clearance, by demonstrating equivalency to Indevus product, without being required to conduct the lengthy and expensive clinical trials required of Indevus. Certain of its agreements provide for reduced royalties, or forgo royalties altogether, in the event of generic competition.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before a potential product can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization, reducing any advantage of the patent.

Indevus license for SANCTURA, a compound approved for use in the treatment of overactive bladder, does not include any patents that it expects to use in the commercialization of the product for overactive bladder. It does not otherwise currently own or have a license to issued patents that cover its SANCTURA product.

Indevus business may be materially adversely affected if it fails to obtain and retain needed patents, licenses or proprietary information. Others may independently develop similar products. Furthermore, litigation may be necessary:

to enforce any of its patents;

to determine the scope and validity of the patent rights of others; or

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in response to legal action against Indevus claiming damages for infringement of patent rights or other proprietary rights or seeking to enjoin commercial activities relating to the affected product or process.

The products marketed by Indevus or its licensees or being developed by Indevus may infringe patents issued to competitors, universities or others. Third parties could bring legal actions against Indevus or its sublicensees claiming patent infringement and seeking damages or to enjoin manufacturing and marketing of the affected product or the use of a process for the manufacture of such products. If any such actions are successful, in addition to any potential liability for indemnification, damages and attorneys fees in certain cases, Indevus could be required to obtain a license, which may not be available, in order to continue to manufacture or market the affected product or use the affected process. If a license is not available to Indevus, it may be forced to abandon the related product. The outcome of any litigation may be uncertain. Any litigation may also result in significant use of management and financial resources.

Indevus also relies upon unpatented proprietary technology and may determine in some cases that its interest would be better served by reliance on trade secrets or confidentiality agreements rather than patents. No assurance can be made that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to such proprietary technology or disclose such technology or that it can meaningfully protect its rights in such unpatented proprietary technology. It may also conduct research on other pharmaceutical compounds or technologies, the rights to which may be held by, or be subject to, patent rights of third parties. Accordingly, if products based on such technologies are commercialized, such commercial activities may infringe such patents or other rights, which may require Indevus to obtain a license to such patents or other rights.

To the extent that consultants, key employees or other third parties apply technological information independently developed by them or by others to Indevus proposed products, disputes may arise as to the proprietary rights to such information which may not be resolved in Indevus favor. Most of its consultants are employed by or have consulting agreements with third parties and any inventions discovered by such individuals will not necessarily become Indevus property. There is a risk that other parties may breach confidentiality agreements or that Indevus trade secrets become known or independently discovered by competitors, which could adversely affect Indevus.

#### Indevus may depend on market exclusivity for certain of its products.

Assuming regulatory approvals are obtained, Indevus ability to commercialize successfully certain drugs may depend on the availability of market exclusivity or patent extension under the Waxman-Hatch Act, which provides protections for certain new products. Under the Waxman-Hatch Act, a company may obtain five years of market exclusivity if the FDA determines such compound to be a chemical entity that has not been the subject of an approved NDA in the past. The period of market exclusivity under the Waxman-Hatch Act is considerably shorter than the exclusivity period afforded by patent protection, which, in the case of some patents, may last up to twenty years from the earliest priority date of the patent directed to the product, its use or method of manufacture. Indevus is relying on market exclusivity under the Waxman-Hatch Act for SANCTURA.

#### Indevus products may be unable to compete successfully with other products.

Competition from other pharmaceutical companies is intense and is expected to increase. Indevus is aware of existing products and of products under development by its competitors that address diseases it is targeting and competitors have developed or are developing products or technologies that are, or may compete with Indevus products.

Many of the other companies who market or are expected to market competitive drugs or other products are large, multinational companies who have substantially greater marketing and financial resources and experience than Indevus. Indevus may not be able to develop products that are more effective or achieve greater market acceptance than competitive products. In addition, Indevus competitors may develop products that are safer or more effective or less expensive than those it is developing or that would render its products less competitive or obsolete. As a result, Indevus products may not be able to compete successfully. In addition, royalties payable to

Indevus under certain conditions may be reduced or eliminated if there is generic competition. In the event its products were unable to be sold at the rate Indevus currently anticipates, it could potentially have excess inventory, resulting in an impairment charge that could have material effect on its financial statements.

Many companies in the pharmaceutical industry also have substantially greater experience in undertaking pre-clinical and clinical testing of products, obtaining regulatory approvals and manufacturing and marketing products. In addition to competing with universities and other research institutions in the development of products, technologies and processes, Indevus competes with other companies in acquiring rights and establishing collaborative agreements for the development and commercialization of its products.

# To be successful, its product candidates must be accepted by the health care community, which can be very slow to adopt or unreceptive to new products.

Indevus product candidates, if approved for marketing, may not achieve market acceptance since hospitals, physicians, patients or the medical community in general may decide not to accept or utilize the associated products. The product candidates that Indevus is attempting to develop differ from established treatment methods and will compete with a number of more established drugs and therapies manufactured and marketed by major pharmaceutical companies.

#### Indevus could be materially harmed if its agreements were terminated.

Indevus agreements with licensors and licensees generally provide the other party with rights to terminate the agreement, in whole or in part, under certain circumstances. Many of its agreements require Indevus to diligently pursue development of the underlying product or risk loss of the license or incur penalties. Depending upon the importance to Indevus of the product that is subject to any such agreement, this could materially adversely affect its business. In particular, termination of its agreements with Madaus or Esprit, related to SANCTURA and SANCTURA XR, its agreement with Aventis, under which it licenses pagoclone, or its agreements with Schering, under which it licenses NEBIDO, could substantially reduce the likelihood of successful commercialization of Indevus product candidates which would materially harm it. The agreements with Esprit, Madaus, Aventis or Schering may be terminated by any of them if Indevus is in material breach of its agreements with them or if it becomes insolvent or files for bankruptcy protection.

#### Indevus depends upon key personnel and consultants.

Indevus has a small number of employees and are dependent on certain executive officers and scientific personnel, including Dr. Glenn L. Cooper, its Chief Executive Officer, Thomas F. Farb, its President and Chief Operating Officer, Noah D. Beerman, its Chief Business Officer, Mark S. Butler, its Chief Administrative Officer and General Counsel, Michael W. Rogers, its Chief Financial Officer, Dr. Bobby W. Sandage, Jr., its Chief Scientific Officer, and John H. Tucker, its Chief Sales and Marketing Officer. Indevus business could be adversely affected by the loss of any of these individuals. In addition, it relies on the assistance of independent consultants to design and supervise clinical trials and prepare FDA submissions.

Competition for qualified employees among pharmaceutical and biotechnology companies is intense, and the loss of any qualified employees, or an inability to attract, retain and motivate highly skilled employees, could adversely affect Indevus business and prospects. Competition to attract and retain pharmaceutical sales people is intense. Indevus may not be able to attract additional qualified employees or retain its existing personnel.

#### Indevus has product liability exposure and insurance uncertainties related to its products.

The use of products in clinical trials and the marketing of products may expose Indevus to substantial product liability claims and adverse publicity. Certain of its agreements require it to obtain specified levels of insurance coverage, naming the other party as an additional insured. Indevus currently maintains product liability

and clinical trial insurance in the amount of \$40,000,000. Indevus may obtain additional coverage for products that may be marketed in the future, including SANCTURA XR and NEBIDO. Indevus may not be able to maintain or obtain insurance coverage, or to obtain insurance in amounts sufficient to protect it or other named parties against liability, at a reasonable cost, or at all. In addition, any insurance obtained may not cover any particular liability claim. Indevus has indemnified certain licensors, licensees and contractors and may be required to indemnify additional licensors, licensees or contractors against product liability claims incurred by them as a result of products Indevus develops or markets. If uninsured or insufficiently insured product liability claims arise, or if a successful indemnification claim was made against Indevus, its business and financial condition could be materially adversely affected. In addition, any payments made by Indevus in connection with product liability litigation could result in significant charges to operations and would materially adversely affect its results of operations and financial condition.

# If third parties on which Indevus relies for clinical trials services do not perform as contractually required or as Indevus expects, it may not be able to obtain regulatory approval for or commercialize its product candidates.

Indevus depends on independent clinical investigators, contract research organizations and other third-party service providers to conduct the clinical trials of its product candidates and expect to continue to do so. Indevus relies heavily on these parties for successful execution of its clinical trials, but it does not control many aspects of their activities. Nonetheless, Indevus is responsible for confirming that each of its clinical trials is conducted in accordance with the general investigational plan and protocol. Indevus reliance on these third parties that it does not control does not relieve it of its responsibility to comply with the regulations and standards of the FDA relating to good clinical practices. Third parties may not complete activities on schedule or may not conduct Indevus clinical trials in accordance with regulatory requirements or the applicable trials plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of its product candidates or result in enforcement action against Indevus.

#### **Risks Related to Indevus Common Stock and Other Securities**

#### Indevus may issue preferred stock with rights that could affect your rights and prevent a takeover of the business.

Indevus board of directors has the authority, without further approval of its stockholders, to fix the rights and preferences, and to issue up to 5,000,000 shares of preferred stock, 244,425 of which are currently issued and outstanding. In addition, vesting of shares of Indevus common stock subject to awards under its 2004 Equity Incentive Plan accelerates and outstanding options under its stock option plans become immediately exercisable upon certain changes in control of Indevus, except under certain conditions. In addition, Delaware corporate law imposes limitations on certain business combinations. These provisions could, under certain circumstances, delay or prevent a change in control of Indevus and, accordingly, could adversely affect the price of its common stock.

#### Indevus have never paid any dividends on its common stock.

Indevus has not paid any cash dividends on its common stock since inception and do not expect to do so in the foreseeable future. Any dividends on its common stock will be subject to the preferential cumulative annual dividend of \$0.1253 per share and \$1.00 per share payable on its outstanding Series B preferred stock and Series C preferred stock, respectively, held by Wyeth and dividends payable on any other preferred stock Indevus may issue.

# If Indevus pays cash dividends on its common stock, certain holders of its securities may be deemed to have received a taxable dividend without the receipt of any cash.

If Indevus pays a cash dividend on its common stock which results in an adjustment to the conversion price of its outstanding convertible notes, holders of such notes may be deemed to have received a taxable dividend subject to U.S. federal income tax without the receipt of any cash.

#### The price for its securities is volatile.

The market prices for Indevus securities and for securities of emerging growth companies have historically been highly volatile. Future announcements concerning Indevus or its competitors may have a significant impact on the market price of Indevus securities. Factors which may affect the market price for Indevus securities, among others, include:

market success of SANCTURA;

results of clinical studies and regulatory reviews;

the marketing approval of SANCTURA XR;

results of its NEBIDO Phase III pharmacokinetic study;

partnerships, corporate collaborations and company acquisitions;

announcements by its corporate collaboration partners concerning its products, about which Indevus generally has very limited control, if any, over the timing or content;

changes in the levels it spends to develop, acquire or license new compounds;

market conditions in the pharmaceutical and biotechnology industries;

competitive products;

sales, the possibility of sales, or buybacks of Indevus common stock or other financings;

Indevus results of operations and financial condition including variability in quarterly operating results due to timing and recognition of revenue, receipt of licensing, milestone and royalty payments, regulatory progress and delays and timing and recognition of certain expenses;

changes in proprietary rights of its, or its competitors, products;

Redux-related litigation developments;

public concern as to the safety or commercial value of its products; and

#### general economic conditions.

The high and low sales prices of Indevus common stock as reported by The Nasdaq Global Market were: \$12.83 and \$0.85 for fiscal 2002, \$6.90 and \$1.32 for fiscal 2003, \$10.25 and \$4.86 for fiscal 2004, \$7.45 and \$2.41 for fiscal 2005, and \$6.62 and \$2.52 for fiscal 2006. Indevus common stock is subject to delisting if its stock price drops below the bid price of \$1.00 per share. If it was to fail to meet any of the continued listing requirements for The Nasdaq Global Market, its common stock could be delisted from The Nasdaq Global Market, the effects of which could include limited release of a market price of its common stock, limited liquidity for stockholders and limited news coverage and could result in an adverse effect on the market for its common stock.

The stock markets also experience significant price and volume fluctuation unrelated to the operating performance of particular companies. These market fluctuations may also adversely affect the market price of Indevus common stock.

#### The price for Indevus common stock could be negatively affected if it issues additional shares or if third parties exercise registration rights.

As of March 1, 2007, Indevus had 56,200,285 shares of common stock issued and outstanding. Substantially all of these shares are eligible for sale without restriction. In addition, Wyeth has the right, under certain circumstances, to require Indevus to register for public sale 622,222 shares of common stock issuable to it upon conversion of the Series B and C preferred stock it owns. Indevus has outstanding registration statements

on Form S-3 relating to the resale of Indevus shares of common stock and on Form S-8 relating to shares issuable under its 1989 Stock Option Plan, 1994 Long-Term Incentive Plan, 1995 Employee Stock Purchase Plan, 1997 Equity Incentive Plan, 1998 Employee Stock Option Plan, 2000 Stock Option Plan, and 2004 Equity Incentive Plan. The possibility of sales of such shares, private sales of securities or the possibility of resale of such shares in the public market may adversely affect the market price of its common stock.

### Indevus stockholders could be diluted if it issues its shares subject to options, warrants, convertible notes, stock awards or other arrangements.

As of December 31, 2006, Indevus has reserved the following shares of its common stock for issuance:

10,817,308 shares issuable upon conversion of the \$72,000,000 Convertible Senior Notes issued in July 2003, which are due in July 2008;

12,733,575 shares issuable upon exercise of outstanding options and Performance Stock Awards, certain of which may be subject to anti-dilution provisions which provide for the adjustment to the conversion price and number of shares for option holders if Indevus issues additional securities below certain prices;

622,222 shares upon conversion of preferred stock owned by Wyeth, subject to anti-dilution provisions; and

1,689,509 shares reserved for grant and issuance under its stock option, stock purchase and equity incentive plans. Indevus may grant additional options, warrants or stock awards. To the extent such shares are issued, the interest of holders of its common stock will be diluted.

#### Increased leverage as a result of Indevus convertible debt offering may harm its financial condition and results of operations.

At December 31, 2006, Indevus had \$72,000,000 of outstanding debt reflected in its balance sheet relating to its outstanding Convertible Notes. If the price of its common stock at the time the convertible debt is due does not exceed 150% of conversion price then in effect for a specified period, then Indevus may not be able to redeem the notes to cause a conversion, then Indevus may be obligated to repay the note holders in cash on the July 2008 due date. Indevus may incur additional indebtedness in the future and the Convertible Notes do not restrict its future issuance of indebtedness. Indevus level of indebtedness will have several important effects on its future operations, including, without limitation:

a portion of its cash flow from operations will be dedicated to the payment of any interest required with respect to outstanding indebtedness;

increases in its outstanding indebtedness and leverage will increase its vulnerability to adverse changes in general economic and industry conditions, as well as to competitive pressure; and

depending on the levels of its outstanding debt, its ability to obtain additional financing for working capital, capital expenditures, general corporate and other purposes may be limited.

Indevus ability to make payments of principal and interest on its indebtedness depends upon its future performance, which will be subject to the success of its development and commercialization of new pharmaceutical products, general economic conditions, industry cycles and financial, business and other factors affecting its operations, many of which are beyond its control. If Indevus is not able to generate sufficient cash flow from operations or other sources in the future to service Indevus debt, it may be required, among other things:

to seek additional financing in the debt or equity markets;

to refinance or restructure all or a portion of Indevus indebtedness, including the Convertible Notes;

to sell selected assets; or

to reduce or delay planned expenditures on clinical trials, and development and commercialization activities. Such measures might not be sufficient to enable Indevus to service its debt. In addition, any such financing, refinancing or sale of assets might not be available on economically favorable terms.

#### **Risks Relating to Valera**

#### Risks Related to Valera s Business

# Valera is largely dependent on the success of Vantas, its first product to be approved for commercial sale by the FDA, and Valera cannot be certain that it will be able to successfully expand the commercialization of Vantas.

Valera has invested and will invest a significant portion of its time and resources in the commercialization of Vantas, which was approved for commercial use by the FDA in October 2004. The commercial success of Vantas is dependent on many factors, including building and maintaining a focused sales force, effectively managing Valera s co-promotion relationship with Indevus, generating commercial sales, gaining acceptance of Vantas by patients and the medical community, and obtaining reimbursement from third party payors. All of Valera s net product sales to date have been generated solely from sales of Vantas. Until Valera s product candidates are approved for commercial use, Valera s most significant source of revenue will be sales of Vantas. If Valera is unable to successfully expand the commercialization of Vantas, it may be required to cease or reduce its commercial and manufacturing operations.

#### Valera has a history of operating losses and may not achieve or sustain profitability.

The extent of Valera's future operating losses or profits is highly uncertain, and Valera may not achieve or sustain profitability. Valera's product development and clinical activities will require significant continuing expenditures. Vantas is Valera's only product that has been approved for commercial use by the FDA and that may generate any significant revenues. From its inception through December 31, 2006 Valera has incurred annual operating losses, and, as of December 31, 2006, Valera had an accumulated deficit of approximately \$53.6 million. The majority of the deficit is attributable to research and development expenditures of \$33.2 million, primarily for Vantas and Supprelin-LA. Valera may incur additional operating losses, as it continues its product development and clinical research, and acquires or in-licenses other pharmaceutical products. Although Valera expects its net product sales, together with borrowings under its line of credit and the proceeds from its initial public offering, to fund these expenses, Valera may not generate sufficient revenue from sales of Vantas to meet all of its expenses.

# Valera is dependent on single suppliers for certain services and raw materials, including histrelin, that are necessary for the manufacture of its products. If any of these suppliers fail or are unable to perform in a timely and satisfactory manner, Valera may be unable to manufacture Vantas or some of its product candidates, which could delay sales of Vantas and hinder research and development of Valera s product candidates.

Valera currently relies on single suppliers for histrelin, the active ingredient in Vantas and Supprelin-LA, for valrubicin, the active ingredient in Valstar, for its implantation devices and for sterilization services for its implants, including Vantas. Valea currently has no written agreements with certain of these suppliers. Although Valera has identified alternate sources for certain raw materials and services, these raw materials and services may not be immediately available to Valera. Further, even if these alternative raw materials are immediately available, they must first meet Valera s internal specifications. Consequently, if any of Valera s suppliers are unable or unwilling to supply Valera with these raw materials in sufficient quantities with the correct specifications, or provide services on commercially acceptable terms, Valera may not be able to manufacture

Vantas or its product candidates in a timely manner or at all, which could delay the production or sale of Vantas and hinder the research and development of some of Valera s product candidates. Valera s inability to obtain these raw materials and services for the manufacture of its implants may force it to cease or reduce operations.

Valera has previously experienced disruptions in its manufacturing of Vantas due to issues caused by Valera s supply of histrelin, the active ingredient in Vantas, including a manufacturing disruption during the second and third quarters of 2005 that caused a material decrease in Valera s sales for the third quarter of 2005 and may have an adverse impact on Valera s sales of Vantas in the future and may have resulted in fewer re-implantations in 2006. Further interruptions in Valera s manufacturing process for Vantas or Valera s product candidates may have an adverse impact of Vantas and the development of Valera s product candidates in the future.

Valera has experienced two separate disruptions in its manufacturing of Vantas due to issues caused by Valera's supply of histrelin, the active ingredient in Vantas. In the fourth quarter of 2004, Valera experienced difficulties processing histrelin in its raw, powder form. These difficulties delayed the manufacturing of Vantas for several weeks as Valera's supplier reformulated the histrelin. In the second and third quarters of 2005, Valera experienced an issue with the histrelin used to produce five lots of Vantas. This issue, which was caused by the method by which Valera's supplier formulated the histrelin, ultimately resulted in these five lots not meeting certain quality control specifications and caused a delay in production of approximately six weeks. Valera has resolved each of these issues and has developed additional specifications with its supplier of histrelin in an effort to ensure a more consistent supply of histrelin that meets its needs. However, the disruption Valera experienced in the second and third quarters of 2005 directly impacted Valera's supply of Vantas in the third quarter of 2005 by limiting the amount of finished product available for sale in the quarter to three lots, or approximately 2,400 units. Valera's third quarter sales were 1,747 units, which was less than Valera's sales in the first and second quarters of 2005, in which Valera sold 2,925 units and 3,974 units, respectively.

The interruption in Valera's supply of Vantas in the second and third quarters of 2005 may have an adverse effect on Valera's ability to sell Vantas in the future. In fact, sales of Vantas were lower in the third quarter of 2006 as compared to the other quarters of 2006, in part because of the disruption experienced in 2005 and the resulting lack of implanted patients that returned for a re-implant in 2006. The lack of supply during that period may continue to have an adverse impact on Valera's future sales because physicians may have elected to use alternative treatments during this time frame or may, as a result of this interruption, permanently switch to another product. Additionally, in the future, Valera may experience other disruptions in its manufacturing process for Vantas or its product candidates. Any disruptions Valera may experience may adversely impact sales of Vantas or the development of its product candidates.

The successful commercialization of Vantas and any other products Valera develops will depend on obtaining reimbursement at adequate levels from private health insurers and Medicare/Medicaid for patient use of these products. Valera expects the reimbursement levels for Vantas to continue to decline, which will have an adverse effect on its net product sales.

Sales of pharmaceutical products largely depend on the reimbursement of patients medical expenses by government healthcare programs, such as Medicare and Medicaid, and private health insurers. These third party payors control healthcare costs by limiting both coverage and the level of reimbursement for healthcare products. Third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services and altering reimbursement levels. The levels at which government authorities and private health insurers reimburse physicians or patients for the price they pay for Vantas and other products Valera may develop could affect the extent to which Valera is able to commercialize these products.

Vantas is currently eligible for insurance reimbursement coverage. Sales of Vantas in the first half of 2005 were supported, in part, by favorable Medicare reimbursement rates, which decreased at the beginning of the third quarter of 2005. The favorable reimbursement rates Valera experienced in the first half of 2005 were due to

the fact that Vantas was a new product that did not yet have an established average selling price, or ASP. As a result, Vantas was reimbursed at wholesale acquisition price, which is typically higher than ASP. Vantas received an established ASP effective July 2005, which has resulted in declining reimbursement rates for Vantas.

Valera expects future Medicare reimbursement levels for Vantas to continue to decline, which will have an adverse effect on its net product sales. Reimbursement levels are currently set by the twenty-three Medicare carriers in the United States which, in the aggregate, cover all fifty states. Certain Medicare carriers have a policy which sets the reimbursement rate for Vantas based on Valera's ASP. Other Medicare carriers have a policy that applies the least costly alternative, or LCA, methodology to Vantas. LCA is a payment methodology that allows Medicare carriers to pay the same reimbursement for drugs that have been determined by Medicare to be medically equivalent. Vantas is currently the least costly alternative in the class of LHRH drugs. Further, certain Medicare carriers have a policy which segregates twelve-month products from all other dosages, including one, three, four and six month injectable products, and reimburses at different rates for these two groups of products, or a split policy. Finally, there are some Medicare carriers which state they have a policy which reimburses on an ASP or LCA methodology, but which Valera believes make payments based upon a split policy.

Valera is devoting internal and external resources to determine the impact and fairness of these various policies. In the states where certain Medicare carriers have adopted a split policy, in writing or in practice, Valera is at an economic disadvantage to the injectable products which are reimbursed at higher annual rates. While Valera is challenging the basis for these reimbursement policies with the Medicare carriers, there is no guarantee that its challenge will be successful.

Significant uncertainty generally exists as to the reimbursement status of newly approved healthcare products. Valera s ability to achieve acceptable levels of reimbursement for its product candidates will affect its ability to successfully commercialize, and attract collaborative partners to invest in the development of, its product candidates. Reimbursement may not be available for Vantas or any other products that Valera develops and reimbursement or coverage levels may reduce the demand for, or the price of, Vantas or any other products that Valera may develop. If Valera cannot maintain coverage for Vantas and obtain adequate reimbursement for other products it develops, the market for those products may be limited.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact Valera s ability to profitably sell Vantas and any other products that it develops. These proposals include prescription drug benefit proposals for Medicare beneficiaries and measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. Legislation creating a prescription drug benefit and making certain changes in Medicaid reimbursement has been enacted by Congress and signed by the President. Additionally, Medicare regulations implementing the prescription drug benefit became effective as of January 1, 2006. These and other regulatory and legislative changes or proposals may affect Valera s ability to raise capital, obtain additional collaborators and market Vantas and any other products that it may develop. In addition, in many foreign countries, particularly Canada and the countries of the European Union, the pricing of prescription drugs is subject to government control. If Valera s products to governmental control, Valera s ability to sell Vantas and other products it develops in commercially acceptable quantities at profitable prices may be harmed.

### As a manufacturer of its products, Valera is subject to regulatory requirements. If Valera does not comply with these requirements, the development and sales of its products and its financial performance may be materially harmed.

Pharmaceutical products are required to be manufactured under regulations known as current good manufacturing practice, or cGMP. Before commercializing a new product, manufacturers must demonstrate compliance with the applicable cGMP regulations, which include quality control and quality assurance

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requirements, as well as the maintenance of extensive records and documentation. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding foreign and state authorities, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing for products generated through the use of their technology. In addition, cGMP requirements are constantly evolving, and new or different requirements may apply in the future. After regulatory approvals are obtained, the subsequent discovery of previously unknown problems or the failure to maintain compliance with existing or new regulatory requirements may result in restrictions on the marketing of a product, withdrawal of the product from the market, seizures, the shutdown of manufacturing facilities, injunctions, monetary fines and civil or criminal sanctions.

Valera may also encounter problems with the following:

production yields;

raw materials;

shortages of qualified personnel;

compliance with FDA regulations, including the demonstration of purity and potency;

changes in FDA requirements;

controlling production costs; and

development of advanced manufacturing techniques and process controls.

In addition, Valera is required to register its manufacturing facilities with the FDA and other regulatory authorities. Valera s facilities are subject to inspections confirming compliance with cGMP or other regulations. If Valera fails to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product, or revocation of pre-existing approval for a product, such as Vantas, which would eliminate Valera s sole source of revenue.

#### Valera may not be able to manufacture the Valstar<sup>®</sup> (valrubicin) product or realize a return on its investment in this product candidate.

Valera acquired from Anthra Pharmaceuticals, Inc. certain assets associated with Anthra's valrubicin product for the treatment of bladder cancer, including the NDA filed with the FDA and the right to sell the product in the United States and Canada. This product was withdrawn from the market in 2002 due to a manufacturing problem. Valera may not realize a return on its investment in such assets due to risks related to the lack of intellectual property protection and potential manufacturing difficulties. Even though the FDA has agreed to Valera's reintroduction plan, there is no assurance that the FDA will ultimately approve the re-launch of Valstar or that Valera will be able to successfully implement the re-introduction plan. Further, Valera will not have exclusive rights with respect to the sale of the valrubicin product because the product is not covered by any patents or orphan drug exclusivity. As a result, competitors may compete with Valera by, among other things, introducing a generic version of the product or a similar product that contains the active ingredient, valrubicin.

Although Valera believes that it has identified the cause of the previous manufacturing problem and that it will be able to correct it, there can be no assurance that Valera will be able to correct the problem or that there will not be manufacturing problems in the future. Even if Valera establishes an acceptable manufacturing protocol, Valera s third-party manufacturers may be unable to manufacture the product in sufficient quantities with the correct specifications or in compliance with cGMP or other applicable regulatory requirements. As a result of these risks, Valera may be unable to realize a return on its investment in this product.

Valera has limited sales, marketing and distribution experience and may be unable to successfully commercialize its products.

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Valera has limited experience in marketing, selling, and distributing its products in the United States and abroad. To achieve commercial success, Valera must build on its current marketing and sales force or contract

with other parties, including collaborators, to perform these services for Valera. In fact, in December 2006 Valera entered into a co-promotion agreement with Indevus under which Indevus will co-promote Vantas in the United States. Any revenues that Valera may receive from this co-promotion or other arrangements will depend on the efforts of Indevus or other third parties which may not be successful and are only partially within Valera s control. Valera will be competing with companies that have experienced and well-funded marketing and sales operations. Many of Valera s competitors have been marketing their products for many years longer than Valera has been marketing Vantas. The failure to adequately sell and distribute Vantas or its product candidates, if approved, could impair Valera s net product sales, cash flows from operations and Valera s cash position.

#### Valera may not be able to obtain additional capital that may be necessary for growth and market penetration or to continue its operations.

Valera believes that the net proceeds it received from its initial public offering, together with its existing cash, cash generated from future sales of Vantas, and its line of credit will be sufficient to meet its projected operating requirements for at least the next 12 months. However, Valera may need to raise additional funds through public or private debt or equity financings to acquire new products or product candidates, significantly expand its sales and marketing capabilities, expand its manufacturing capacity, develop product candidates, obtain FDA approval of its product candidates and continue its commercial growth. Any additional equity financings may be on terms that are dilutive or potentially dilutive to Valera s stockholders. Any debt financing Valera enters into may involve incurring significant interest expense and include covenants that restrict Valera s operations. If Valera raises additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to its technologies, product candidates or products, or grant licenses on terms that are not favorable to Valera. Valera s ability to raise additional funds will depend on financial, economic and market conditions and other factors, many of which are beyond its control. Valera may not be able to obtain financing on acceptable terms or at all. If financing is insufficient or unavailable, Valera will have to modify its growth and marketing strategies and scale back operations by delaying, reducing the scope of, or eliminating one or more of its planned development, commercialization or expansion activities. This may negatively affect Valera s ability to expand its commercialization of vantas and develop and bring new products to market, which could have a material adverse effect on its business, financial condition and results of operations.

Valera s future capital requirements may be significantly greater than it expects and depend on many factors, including:

costs associated with conducting pre-clinical and clinical testing;

costs associated with commercializing Vantas and other products it may develop, including expanding sales and marketing functions; for example, in connection with Supprelin-LA, Valera expects to increase its sales force;

costs of establishing arrangements for manufacturing;

costs of acquiring new pharmaceutical products and drug delivery systems;

payments required under its current and any future license agreements and collaborations; for example, Valera is required to make certain royalty and co-promotion payments, which are tied to sales of Vantas;

costs, timing and outcome of regulatory reviews;

costs of obtaining, maintaining and defending patents on proprietary technology; and

costs of increased general and administrative expenses.

As of December 31, 2006, the cumulative amount of royalty expense incurred by Valera as a result of sales of Vantas was approximately \$2.5 million.

#### If products utilizing Valera s technology fail to gain market acceptance, Valera may be unable to generate significant revenue.

Even if clinical trials demonstrate the safety and efficacy of products developed utilizing Valera s technology and all regulatory approvals are obtained, such products may not gain market acceptance among physicians, patients, third party payors or the medical community. The current method of administration for Valera s product candidates in late-stage development is implantation, which may be less well received by some patients than injection therapy. The degree of market acceptance of any product employing Valera s technology will depend on a number of factors, including:

establishment and demonstration of clinical efficacy and safety;

cost-effectiveness;

adequate reimbursement by third parties;

relative convenience and ease of administration;

timing of market introduction of competitive products;

alternative treatment methods, for example, injections and oral formulations; and

marketing and distribution support.

If Valera s products do not achieve significant market acceptance, Valera may be unable to generate significant revenue, which could have a material adverse effect on its business, cash flows and results of operations.

#### Valera s failure to recruit, retain, and motivate qualified management and scientific personnel could adversely affect it.

Valera has a small number of employees and is dependent on certain executive officers and scientific personnel, including David S. Tierney, M.D., Valera s President and Chief Executive Officer, Petr F. Kuzma, Vice President of Research and Development, Matthew L. Rue, III, Vice President of Marketing and Commercial Development, and Kevin Pelin, Vice President of Manufacturing Operations. The loss of the services of any member of Valera s senior management, scientific or technical staff may significantly delay or prevent the achievement of drug development and other business objectives, and could have a material adverse effect on Valera s business, financial condition and results of operations. Valera may not be able to recruit and retain qualified personnel in the future due to intense competition for personnel among pharmaceutical businesses, and Valera s failure to do so could delay or curtail its product development efforts, impair its ability to execute its business strategy and adversely affect it. Valera has not purchased any key man life insurance for any of its employees.

Valera also utilizes consultants and advisors to assist it with research and development. All of Valera s consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to Valera, which could have a material adverse effect on Valera s business, financial condition and results of operations.

### Valera faces substantial competition and its competitors may discover, develop or commercialize products similar to Valera s before or more successfully than Valera does.

The biotechnology and pharmaceutical industries are very competitive. Valera competes against all pharmaceutical companies that manufacture or market LHRH agonist products. Valera also competes against biotechnology companies, universities, government agencies, and other research institutions in the development of urological and endocrine products, technologies and processes that are, or in the future may be, the

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basis for competitive commercial products.

In particular, Valera competes against the following LHRH agonist products for the palliative treatment of advanced prostate cancer: TAP Pharmaceutical Products Lupron and Sanofi-Aventis Eligard, both multiple injection formulations that deliver leuprolide; Watson Pharmaceuticals Trelstar, a multiple injection formulation that delivers triptorelin; AstraZeneca s Zoladex, a biodegradable rod that delivers goserelin for up to three months; and Bayer Pharmaceuticals Viadur, a rigid metal implant that releases leuprolide over a 12-month period. With respect to Valera s Supprelin-LA product in late-stage development for the treatment of central precocious puberty, Valera s competitor is TAP Pharmaceutical Products Lupron Depot-PED and with regard to VP003, Valera s octreotide implant for acromegaly, Valera s competitors include Novartis Sandostatin injections and Sandostatin LAR Depots and Pfizer s Somavert.

Many of Valera s competitors have substantially greater financial and other resources, larger research and development staffs and more experience developing products, obtaining FDA and other regulatory approvals and manufacturing and marketing products. In addition, many of Valera s competitors devote significant resources to challenging the marketing policies of other developers of pharmaceutical products. Consequently, competition for the development and marketing of urological and endocrine pharmaceutical products is intense and is expected to increase. For example, in the past Valera has received communications from Bayer Pharmaceuticals regarding Valera s sales and marketing techniques for Vantas. Valera s practice has been to review these communications with counsel to determine whether any remedial or corrective action needs to be made. These communications have not resulted in any notice of violations or other action by any government authority or agency.

Valera s competitors may discover, develop or commercialize products similar to Valera s before or more successfully than Valera does and may compete with Valera in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to Valera s programs or advantageous to Valera s business. In addition, there may be product candidates of which Valera is not aware at an earlier stage of development that may compete with its product candidates. If any of them are successfully developed and approved, they could compete directly with Valera s product candidates. This could result in reduced sales and pricing pressure on any similar products that Valera develops, which in turn would reduce Valera s ability to generate revenue and could have a material adverse effect on Valera s net product sales, gross margin and cash flows from operations.

#### Valera s sales of Vantas and any other products it may develop could suffer from competition by generic products.

Although Valera has proprietary protection for Vantas and other products it is developing, Valera could face competition from generic substitutes of these products if generics are developed by other companies and approved by the FDA. Because generic manufacturers are not exposed to development risks for such generic substitutes, these manufacturers can capture market share by selling generic products at lower prices, which can reduce the market share held by the original product. Competition from the sale of generic products may cause a decrease in Valera's selling price or units sold, and could have a material adverse effect on Valera's net product sales, gross margin and cash flows from operations.

#### Valera faces a risk of product liability claims and may not be able to obtain adequate insurance.

Valera s business exposes it to potential liability risks that may arise from the clinical testing of its product candidates and the manufacture and sale of Vantas and other products that it may develop. Plaintiffs have received substantial damage awards in some jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. Such liability claims may be expensive to defend and may result in large judgments against Valera. Although Valera has liability insurance with a coverage limit of \$10 million, its insurance may not reimburse it, or this coverage may not be sufficient to cover claims that may be made against Valera. In addition, if Valera is no longer able to maintain this coverage or have to obtain additional coverage, it may not be able to obtain liability insurance on acceptable terms or at all. Whether or not

Valera is ultimately successful in any product liability litigation, such litigation could consume substantial amounts of Valera s financial and managerial resources and could result in:

significant awards against Valera;

substantial litigation costs;

recall of the product;

injury to Valera s reputation; and

withdrawal of clinical trial participants;

all of which could have a material adverse effect on Valera s business, financial condition and results of operations.

# The approved drugs used in Vantas and Valera s product candidates, as well as the implant itself, may cause side effects and Valera may not be able to achieve an acceptable level of side effect risks, compared to the potential therapeutic benefits, for its product candidates.

The active compound in Vantas and each of Valera s product candidates has been approved by the FDA for the treatment of the conditions, diseases and disorders that Valera is seeking to treat. Each of these compounds, as well as the implant itself and other delivery methods, is associated with certain side effects. Although Valera has not experienced any difficulties with the side effects profile of Vantas, the implant or its product candidates to date, the side effects of the approved drugs in its product candidates may be acceptable when a drug is used in its approved dosage to achieve a therapeutic benefit for its currently approved indications, but the side effects of the approved drugs, the implant or the combination of these elements, could prevent successful development and commercialization of some or all of Valera s product candidates.

Further, Valera s development of a product candidate could be adversely affected by safety or efficacy issues that subsequently arise regarding use of the approved drug, similar drugs or the implant or other delivery method. Valera could be forced to abandon a product candidate or an approved product, such as Vantas, due to adverse side effects from long-term or other use of the implant or other delivery method or the active pharmaceutical ingredients in the product candidate or product.

#### **Risks Related to Clinical Trials and Other Regulatory Matters**

# If Valera s clinical trials are unsuccessful or significantly delayed, or if Valera does not complete its clinical trials, Valera may not be able to commercialize its product candidates.

Valera must provide the FDA and similar foreign regulatory authorities with pre-clinical and clinical data to demonstrate that its product candidates are safe and effective for each indication before they can be approved for commercialization. The pre-clinical testing and clinical trials of any product candidates that Valera develops must comply with the regulations of numerous federal, state and local government authorities in the United States, principally the FDA, and by similar agencies in other countries. Clinical development is a long, expensive and uncertain process and is subject to delays. Valera may encounter delays or rejections for various reasons, including its inability to enroll enough patients to complete its clinical trials.

Valera has various product candidates at various stages of development. It may take several years to complete the testing of a product candidate, and failure can occur at any stage of development, for many reasons, including:

interim results of pre-clinical or clinical studies do not necessarily predict their final results, and acceptable results in early studies might not be seen in later studies;

product candidates that appear promising at early stages of development may ultimately fail because the products may be ineffective, may be less effective than competitors products or may cause harmful side effects;

any pre-clinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities;

pre-clinical or clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval;

negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre-clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful;

the FDA can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;

Valera may encounter delays or rejections based on changes in regulatory agency policies during the period in which it is developing a product candidate or the period required for review of any application for regulatory agency approval;

Valera s clinical trials may not demonstrate the safety and efficacy of any product candidates or result in marketable products;

the FDA may change its approval policies or adopt new regulations that may negatively affect or delay Valera s ability to bring a product candidate to market; and

a product candidate may not be approved for all the indications which Valera requests. The development and approval process may take many years, require substantial resources and may never lead to the approval of a product. With the exception of Vantas, Valera does not have, and may never obtain, the regulatory approvals it needs to market its product candidates. Valera s failure to obtain, or delay in obtaining, regulatory approvals would have a material adverse effect on its business, financial condition and results of operations.

Product candidates are subject to extensive and rigorous government regulation by the FDA, other regulatory agencies, and their respective foreign equivalents. The FDA regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical products. Any of Valera s products marketed abroad will also be subject to extensive regulation by foreign governments, whether or not Valera has obtained FDA approval for a given product and its uses.

Government regulation substantially increases the cost of researching, developing, manufacturing and selling pharmaceutical products. The regulatory review and approval process, which includes pre-clinical testing and clinical trials of each product candidate, is lengthy, expensive and uncertain. Valera must obtain regulatory approval for each product it intends to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish the product safety, efficacy, potency and purity for each intended use. Moreover, approval policies or regulations may change. Valera will not be able to commercialize its product candidates until it obtains FDA approval in the United States or approval by comparable authorities in other countries. The development and approval process takes many years, requires substantial resources and may never lead to the approval of a product. In October 2004, Valera received FDA approval for the commercial sale of Vantas in the United States. In November 2005, Valera received approval to market Vantas in Denmark. In March 2006, Valera received approval to market Vantas in Canada. Failure to obtain, or delays in obtaining, regulatory approvals may:

adversely affect the commercialization of any products that Valera develops;

impose additional costs on Valera;

diminish any competitive advantages that Valera may attain; and

adversely affect Valera s receipt of revenues or royalties. Even if Valera receives regulatory approval for its product candidates, the approval may be limited. Moreover, Valera will be subject to significant ongoing regulatory obligations and oversight.

Even if Valera is able to obtain regulatory approval for a particular product, the approval may limit the indicated uses for the product, may otherwise limit Valera s sales practices and its ability to promote, sell and distribute the product, may require that Valera conduct costly post-marketing surveillance and may require that Valera conduct ongoing post-marketing studies. Material changes to an approved product, such as manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product. If Valera or its contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in:

refusals or delays in the approval of applications or supplements to approved applications;

refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications;

warning letters;

fines;

import or export restrictions;

product recalls or seizures;

injunctions;

total or partial suspension of clinical trials or production;

civil penalties;

withdrawals of previously approved marketing applications or licenses;

recommendations by the FDA or other regulatory authorities against entering into governmental contracts with Valera; or

criminal prosecutions.

# The regulatory approval process outside the United States varies depending on foreign regulatory requirements, and failure to obtain regulatory approval in foreign jurisdictions would prevent the marketing of Valera s products in those jurisdictions.

Valera intends to also market its products outside of the United States. For example, Valera has executed agreements to license Vantas in Canada, Europe, South Africa, Asia and Argentina. To market its products in the European Union and many other foreign jurisdictions, Valera must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing that product in those countries. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process includes all of the risks associated with obtaining FDA approval set forth above, and approval by the FDA does not ensure approval by the regulatory authorities in other foreign countries in other foreign countries in other foreign countries or the FDA. Valera may not be able to file for regulatory approvals and may not receive necessary approvals to

commercialize its products in any foreign market. If Valera fails to comply with these regulatory requirements or obtain and maintain required approvals, Valera s target market will be reduced and its ability to generate revenue from abroad will be adversely affected.

# Valera relies on third parties to conduct certain clinical trials for its product candidates, and if they do not perform their obligations, Valera may not be able to obtain regulatory approvals for its product candidates.

Valera designs the clinical trials for its product candidates, but it relies on academic institutions, corporate partners, contract research organizations and other third parties to assist it in managing, monitoring and otherwise carrying out these trials. Accordingly, Valera may have less control over the timing and other aspects of these clinical trials than if it conducted them entirely on its own. Although it relies on these third parties to manage the data from these clinical trials, Valera is responsible for confirming that each of its clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, FDA and foreign regulatory agencies require Valera to comply with regulations and standards, commonly referred to as good clinical practice, for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. Valera s reliance on third parties does not relieve it of these responsibilities and requirements, and Valera may fail to obtain regulatory approval for its product candidates, if these requirements are not met.

#### **Risks Related to Intellectual Property**

### Valera s success depends on the protection of its intellectual property rights and its failure to secure these rights would materially harm its business.

Valera will be able to protect its proprietary rights from unauthorized use by third parties only to the extent that its proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. Valera protects its proprietary position by filing United States and foreign patent applications related to its proprietary technology, inventions and improvements that are important to the development of its business. Valera may not be able to obtain patent protection for its pending patent applications, those it may file in the future, or those it may license from third parties. Moreover, patents issued or that may be issued or licensed may not be enforceable or valid or may expire prior to the commercialization of its product candidates. The patent position of a pharmaceutical company involves complex legal and factual questions and, therefore, enforceability or validity cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that Valera owns or licenses from third parties may not provide sufficient protection against Valera s competitors. Also, patent rights may not provide Valera with proprietary protection or competitive advantages against competitors with similar technology. Further, the laws of foreign countries may not protect Valera s intellectual property rights to the same extent as do the laws of the United States.

# If Valera is unable to protect the confidentiality of its proprietary information and know-how, its competitive position would be impaired and its business could be adversely affected.

In addition to patent protection, Valera also relies on the protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, Valera has entered into confidentiality agreements with its employees, consultants and collaborators upon the commencement of their relationships with it. These agreements require that all confidential information developed by the individual or made known to the individual by Valera during the course of the individual s relationship with Valera be kept confidential and not disclosed to third parties. Valera s agreements with employees also provide that inventions conceived by the individual in the course of rendering services to Valera shall be Valera s exclusive property. However, Valera may not obtain these agreements in all circumstances, and individuals with whom Valera has these agreements may not comply with the terms of these agreements. In the event of unauthorized use or disclosure of Valera s trade secrets or proprietary information. Further, to the extent that its employees, consultants or contractors use technology or know-how owned by others in their work for Valera, disputes may arise as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of Valera s confidential information. The disclosure of Valera s trade secrets would impair its competitive position and could harm its business.

# Valera s commercial success depends significantly on its ability to operate without infringing the patents and other proprietary rights of third parties.

Others may obtain patents that could limit Valera s ability to use, import, manufacture, market or sell products or impair its competitive position. No patent can protect its holder from a claim of infringement of another patent. Therefore, Valera s patent position cannot and does not provide any assurance that the commercialization of its products would not infringe the patent rights of another. In the event its technologies infringe or violate the proprietary rights of third parties, Valera may be prevented from pursuing the development, manufacturing or commercialization of its products that utilize such technologies. While Valera knows of no actual or threatened claim of infringement that would be material to it, there can be no assurance that such a claim will not be asserted. If such a claim is asserted, the resolution of the claim may not permit Valera to continue marketing the relevant product, such as Vantas, on commercially reasonable terms, if at all.

#### Protecting Valera s intellectual property is expensive and time consuming and could harm its business.

Third parties may challenge the validity of Valera s patents and other intellectual property rights, resulting in costly litigation or other time-consuming and expensive proceedings, which could deprive Valera of valuable rights. If Valera becomes involved in any intellectual property litigation, interference or other judicial or administrative proceedings, it will incur substantial expenses and the diversion of financial resources and technical and management personnel. An adverse determination may subject Valera to significant liabilities or require it to seek licenses that may not be available from third parties on commercially favorable terms, if at all. Further, if such claims are proven valid, through litigation or otherwise, Valera may be required to pay substantial financial damages, which can be tripled if the infringement is deemed willful, or be required to discontinue or significantly delay development, marketing, selling and licensing of the affected products and intellectual property rights. In addition, an adverse determination in a proceeding involving Valera s owned or licensed intellectual property may allow entry of generic substitutes for its products.

#### Risks Related to Valera s Common Stock

#### The trading price of the shares of Valera s common stock could be highly volatile.

The trading price of the shares of Valera s common stock could be highly volatile in response to various factors, many of which are beyond Valera s control, including:

developments concerning Vantas or any of Valera s product candidates;

announcements of technological innovations by Valera or its competitors;

new products introduced or announced by Valera or its competitors;

changes in reimbursement levels;

changes in financial estimates by securities analysts;

actual or anticipated variations in operating results;

expiration or termination of licenses, research contracts or other collaboration agreements;

conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;

intellectual property, product liability or other litigation against Valera;

Valera s failure to consummate the proposed merger with Indevus;

changes in the market valuations of similar companies; and

sales of shares of Valera s common stock, particularly sales by Valera s officers, directors and significant stockholders. In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. In addition, changes in economic conditions in the United States, Europe or globally, could impact upon Valera s ability to grow profitably. Adverse economic changes are outside Valera s control and may result in material adverse impacts on Valera s business or results. These broad market and industry factors may materially affect the market price of the shares, regardless of Valera s development and operating performance. In the past, following periods of volatility in the market price of a company s securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against Valera could cause Valera to incur substantial costs and divert management s attention and resources, which could have a material adverse effect on Valera s business, financial condition and results of operations.

# The ownership interests of Valera's officers, directors and largest stockholders could conflict with the interests of Valera's other stockholders.

Valera's directors, executive officers and holders of 5% or more of its outstanding common stock beneficially own approximately 58% of Valera's common stock as of March 1, 2007. As a result, these stockholders, acting together, are able to significantly influence all matters requiring approval by Valera's stockholders, including the election of directors and approval of mergers or other significant corporate transactions. For example, in connection with Valera's proposed merger with Indevus, certain affiliated funds of Sanders Morris Harris, Valera's largest stockholder, and one other large stockholder of Valera's, entered into voting agreements with Indevus in which they have agreed to vote shares representing approximately 41% of Valera's outstanding shares of common stock in favor of the merger. The interests of this group of stockholders may not always coincide with Valera's interests or the interests of other stockholders.

#### Valera s use of its initial public offering proceeds may not yield a favorable return on your investment.

Valera has used a portion of the net proceeds from its initial public offering to expand its sales and marketing capabilities, fund its research and development activities, expand its manufacturing capabilities, and for general corporate purposes, including the potential acquisition or in-license of additional urological and endocrine products. Valera has used a portion of the net proceeds from its initial public offering to repay amounts outstanding under its line of credit. In addition, Valera may use a portion of the net proceeds to acquire businesses, products or technologies that are complementary to its current or future business and product lines. Valera s management has broad discretion over how these proceeds are used and could spend the proceeds in ways with which you may not agree. Valera also plans to invest the proceeds from its initial public offering. However, the proceeds may not be invested effectively or in a manner that yields a favorable or any return, and consequently, this could result in financial losses that could have a material adverse effect on Valera s business, cause the price of its common stock to decline and/or delay the development of its product candidates.

#### Valera s common stock has been publicly traded for a short time and an active trading market may not be sustained.

Although Valera is currently listed for trading on The Nasdaq Global Market, an active trading market for its common stock may not be sustained. An inactive market may impair your ability to sell shares of Valera s common stock at the time you wish to sell them or at a price that you consider reasonable. Furthermore, an inactive market may impair Valera s ability to raise capital by selling additional shares and may impair Valera s ability to acquire other businesses, products and technologies by using its shares as consideration.

Delaware law and Valera s amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay and discourage takeover attempts that stockholders may consider favorable.

Certain provisions of Valera s amended and restated certificate of incorporation, or certificate of incorporation, and amended and restated bylaws, or bylaws, and applicable provisions of Delaware corporate law may make it more difficult for or prevent a third party from acquiring control of Valera or changing Valera s board of directors and management. These provisions include:

the ability of Valera s board of directors to issue preferred stock with voting or other rights or preferences;

limitations on the ability of stockholders to amend Valera s charter documents, including stockholder supermajority voting requirements;

the inability of stockholders to act by written consent or to call special meetings;

a classified board of directors with staggered three-year terms;

requirements that special meetings of Valera s stockholders may only be called by the chairman of Valera s board of directors, Valera s president, or upon a resolution adopted by, or an affirmative vote of, a majority of Valera s board of directors; and

advance notice procedures Valera s stockholders must comply with in order to nominate candidates for election to Valera s board of directors or to place stockholders proposals on the agenda for consideration at meetings of Valera s stockholders. Valera will also be afforded the protections of Section 203 of the Delaware General Corporation Law, which will prevent Valera from engaging in a business combination with a person who acquires at least 15% of Valera s common stock for a period of three years from the date such person acquired such common stock, unless board or stockholder approval were obtained. Because Valera s board of directors approved the Indevus merger and the agreements executed in connection with the merger, Section 203 will not apply to the merger if it is approved and becomes effective.

Any delay or prevention of a change of control transaction or changes in Valera s board of directors or management could deter potential acquirors or prevent the completion of a transaction in which Valera s stockholders could receive a substantial premium over the then current market price for their shares.

#### Future sales of Valera s common stock may depress its stock price.

Persons who were Valera stockholders prior to the sale of shares in Valera s initial public offering continue to hold a substantial number of shares of Valera s common stock that they will be able to sell in the public market in the near future. Significant portions of these shares are held by a small number of stockholders. Sales by Valera s current stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of Valera s common stock. Moreover, the holders of approximately 9,406,271 shares of Valera s common stock as of March 1, 2007, will have rights, subject to certain conditions, to require Valera to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that Valera may file for itself or other stockholders.

# Valera s quarterly financial results are likely to fluctuate significantly because Valera s sales prospects are uncertain and, as a result, Valera s stock price may decline.

Valera s quarterly operating results are difficult to predict and may fluctuate significantly from period to period. For example, as described above, less favorable reimbursement rates of Vantas became effective at the beginning of the third quarter of 2005, as the basis for determining reimbursement rates switched from wholesale acquisition cost to the typically lower ASP. In addition, as described above, Valera anticipates that

the number of

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states that provide reimbursement for Vantas under the Medicare program using the LCA methodology will increase in future quarters, leading to a decline in Valera s sales price for Vantas. The level of Valera s revenues and results of operations at any given time will be based primarily on the following factors:

the effectiveness of Valera s co-promotion relationship with Indevus;

success of the commercialization of Vantas and any other product candidates that may be approved;

Valera s ability to license its implant technology;

changes in Valera s ability to obtain FDA approval for Valera s product candidates;

results of Valera s clinical trials;

timing of new product offerings, acquisitions, licenses or other significant events by Valera or its competitors;

regulatory approvals and legislative changes affecting the products Valera may offer or those of Valera s competitors;

Valera s ability to establish, grow and maintain a productive sales force;

demand and pricing of Vantas and other products Valera may offer;

physician and patient acceptance of Vantas and other products Valera may offer;

levels of third-party reimbursement for Vantas and other products Valera may offer;

interruption in the manufacturing or distribution of Vantas and other products Valera may offer; and

the effect of competing technological and market developments. It will be difficult for Valera to forecast demand for Vantas and its product candidates that may be approved with any degree of certainty, and therefore, Valera's sales prospects are uncertain. In addition, Valera will be increasing its operating expenses as it expands its commercial capabilities. Accordingly, Valera may experience significant, unanticipated quarterly losses. Because of these factors, Valera's operating results in one or more future quarters may fail to meet the expectations of securities analysts or investors, which could cause Valera's stock price to decline significantly.

#### INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This document contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve a number of risks and uncertainties. Indevus and Valera caution readers that any forward-looking statement is not a guarantee of future performance and that actual results could differ materially from those contained in the forward-looking statement. These statements are based on current expectations of future events. Such statements include, but are not limited to, statements about the anticipated benefits of the merger between Indevus and Valera, including future financial and operating results, the combined company s plans, objectives, expectations and intentions, costs and expenses, interest rates, outcome of contingencies, financial condition, results of operations, liquidity, business strategies, cost savings, objectives of management and other statements that are not historical facts. You can find many of these statements by looking for words like believes, expects, anticipates, estimates, may, should, will, could, plan, intend or s in this document or in documents incorporated by reference in this document.

These forward-looking statements are based on the current beliefs and expectations of Indevus and Valera's management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results may differ materially from current expectations and projections. The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements:

the risk factors described above under the heading Risk Factors ;

the potential inability of the two companies to close the merger, successfully execute their integration strategies or achieve planned synergies;

uncertainties regarding the two companies future operating results, and the risk that future sales of SANCTURA, DELATESTRYL, Vantas and other of the companies products may be less than expected;

changes in reimbursement policies and or rates for the companies products;

the impact of current, pending or future legislation, regulations and legal actions in the United States and elsewhere affecting the pharmaceutical and healthcare industries;

currency fluctuations in the two companies primary markets;

the timing, expense and uncertainty associated with the development and regulatory approval process for products;

the safety and effectiveness of the two companies products and technologies;

the dependence on third parties to develop and commercialize select product candidates;

the ability of Indevus and Valera to successfully protect and enforce their respective intellectual property rights;

the reliance on third party manufacturers or the ability to manufacture products;

the timing and expense associated with compliance with regulatory requirements;

general competitive conditions within the drug development and pharmaceutical industry; and

general economic conditions.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this document or, in the case of documents referred to or incorporated by reference, the dates of those documents.

All subsequent written or oral forward-looking statements attributable to Indevus or Valera or any person acting on any of their behalves are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. Neither Indevus nor Valera undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events, except as may be required under applicable U.S. securities law.

#### THE INDEVUS ANNUAL AND SPECIAL MEETING

Indevus is furnishing this document to holders of Indevus common stock in connection with the solicitation by Indevus board of directors of proxies to be voted at the annual and special meeting of Indevus stockholders to be held on April 17, 2007, and at any adjournment or postponement of the annual and special meeting.

This document is first being mailed to Indevus stockholders on or about March 14, 2007.

#### Date, Time and Place of Meeting

The annual and special meeting will be held on April 17, 2007, at 11:00 a.m., local time, at The Conference Center at Waltham Woods, 860 Winter Street, Waltham, MA 02451.

#### Purpose of the Annual and Special Meeting

The purpose of the Indevus annual and special meeting is to consider and vote upon the following proposals:

1. To approve the issuance of Indevus common stock and contingent stock rights in connection with the merger contemplated by the Agreement and Plan of Merger, dated as of December 11, 2006, by and among Indevus, Merger Sub (which is a wholly-owned subsidiary of Indevus) and Valera, a copy of which is included as *Annex A* to this joint proxy statement/prospectus;

2. To elect eight members of Indevus board of directors to serve until the 2008 annual meeting of stockholders and until their successors are elected and qualified;

3. To approve an amendment to Indevus Restated Certificate of Incorporation to increase the number of authorized shares of Indevus common stock from 120 million to 200 million;

4. To approve an amendment to Indevus 2004 Equity Incentive Plan to increase the number of shares of common stock reserved for issuance under the plan from 6,000,000 to 9,000,000;

5. To approve an amendment to Indevus 2004 Equity Incentive Plan to remove the 20% limitation on the number of certain types of awards that can be made with respect to the additional 3,000,000 shares proposed to be added to the plan as set forth above;

6. To approve an amendment to Indevus 1995 Stock Purchase Plan to increase the number of shares of Indevus common stock available for purchase under the plan from 800,000 to 1,050,000; and

7. To ratify the appointment of PricewaterhouseCoopers LLP as Indevus independent registered public accounting firm.

# The approval of Proposal No. 1 is a condition to the completion of the merger. Accordingly, if Indevus stockholders wish to approve the merger, they must approve Proposal No. 1.

Indevus stockholders also will be asked to transact any other business that may be properly brought before the annual and special meeting or any adjournments or postponements of the annual and special meeting. At this time, Indevus board of directors is unaware of any matters, other than the proposals set forth above, that may properly come before the annual and special meeting.

#### **Record Date; Shares Outstanding and Entitled to Vote**

Indevus has fixed the close of business on March 12, 2007, as the record date for the determination of holders of shares of Indevus common stock, par value \$0.001 per share, and holders of shares of Indevus Series B preferred stock and Series C preferred stock, par value \$0.001 per share, which we refer to collectively as preferred stock, entitled to notice of, and to vote at, the annual and special meeting, and any adjournment or postponement of the annual and special meeting, on all matters, except that the holders of preferred stock are not entitled to vote for the election of directors.

In deciding all matters that come before the annual and special meeting, each holder of Indevus common stock is entitled to one vote per share of Indevus common stock held as of the close of business on the record date. In deciding all matters that come before the annual and special meeting, other than the election of directors for which preferred stock is not entitled to vote, the holders of the Series B Preferred Stock and Series C Preferred Stock are entitled to cast an aggregate of 568,850 votes relating to the 622,222 shares of common stock issuable upon conversion of the respective shares of preferred stock. The holders of the common stock and preferred stock vote together as a single class, except for those matters on which holders of common stock or the holders of preferred stock are entitled to vote as a separate class.

At the close of business on the record date for the annual and special meeting, there were outstanding and entitled to vote 56,202,160 shares of Indevus common stock held by approximately 590 holders of record. In addition, at the close of business on the record date for the annual and special meeting there were outstanding 239,425 shares of Series B Preferred Stock and 5,000 shares of Series C Preferred Stock, which, on an as-if-converted basis, are entitled to an aggregate of 568,850 votes on all matters at the annual and special meeting, other than the election of directors. There are no other shares of Indevus capital stock entitled to notice of and to vote at the annual and special meeting. Accordingly, the aggregate number of votes of Indevus common stock and preferred stock that may be cast at the annual and special meeting for all matters (other than the election of directors) is 56,771,010.

#### **Quorum; Abstentions and Broker Non-Votes**

A quorum, consisting of 28,101,081 shares of Indevus common stock, which is a majority of the outstanding shares of Indevus common stock entitled to vote, must be represented at the annual and special meeting in person or by proxy before any action may be taken with respect to the election of directors at the annual and special meeting. As to all other matters, a quorum, consisting of 28,385,506 shares of Indevus common stock and preferred stock (on an as-if-converted basis), which is a majority of the aggregate number of shares of Indevus common stock and preferred stock (on an as-if-converted basis) outstanding and entitled to vote, must be represented at the annual and special meeting in person or by proxy before any action may be taken. Abstentions and broker non-votes will be counted as shares that are present and entitled to vote for purposes of determining the presence of a quorum.

An abstention occurs when a stockholder sends in a proxy with explicit instructions to decline to vote regarding a particular matter. Broker non-votes are shares held by brokers or nominees for which voting instructions have not been received from the beneficial owners or the persons entitled to vote those shares and the broker or nominee does not have discretionary voting power under rules applicable to broker-dealers. If you hold your shares of Indevus common stock through a broker, bank or other nominee, generally the nominee may only vote your shares in accordance with your instructions. However, if your broker, bank or other nominee has not timely received your instructions, it may vote on matters for which it has discretionary voting authority. Under rules applicable to broker-dealers, the proposal to issue Indevus common stock in connection with the merger, and the proposals relating to the amendments to the 2004 Equity Incentive Plan and the 2005 Employee Stock Purchase Plan are not matters on which brokerage firms may vote in their discretion on behalf of their clients if such clients have not furnished voting instructions within ten days of the annual and special meeting. The proposals to elect eight members of Indevus common stock and to ratify the appointment of PricewaterhouseCoopers LLP as Indevus independent registered public accounting firm are matters on which brokerage firms may vote in their clients, even if such clients have not furnished voting instructions.

Abstentions will have the same effect as a vote against the proposal to amend Indevus Restated Certificate of Incorporation and will have no effect on the outcome of any of the other proposals to be considered at the Indevus stockholders meeting. Broker non-votes will have no effect on the outcome of any proposals to be considered at the Indevus stockholders meeting.

#### **Required Votes**

*Proposal No. 1:* Under the rules of The Nasdaq Global Market, on which Indevus common stock is listed, the proposal to approve the issuance of Indevus common stock and CSRs pursuant to the merger agreement requires Indevus stockholder approval because the number of shares of Indevus common stock to be issued in the merger will exceed 20% of the number of shares of Indevus common stock outstanding immediately prior to the merger. The affirmative vote of the total number of votes cast on the proposal (with Indevus common stock and preferred stock voting together as a single class) is required to approve the issuance of Indevus common stock and CSRs pursuant to the merger agreement. Since the required vote to approve the issuance of Indevus common stock in connection with the merger is based on the number of votes cast at the annual and special meeting, abstentions and broker non-votes will have no effect on the outcome of the proposal. **The approval of Proposal No. 1 is a condition to the completion of the merger, and thus a vote against this proposal effectively will be a vote against the merger.** 

*Proposal No. 2:* The affirmative vote of a plurality of votes cast by the holders of Indevus common stock (with preferred stock not entitled to vote on this matter) represented at the annual and special meeting and entitled to vote is necessary to elect the directors. With respect to the election of directors, there will be no broker non-votes because brokerage firms may vote in their discretion on behalf of clients on this proposal even if such clients have not furnished voting instructions with respect to this proposal. Abstentions will have no effect in determining whether a director has been elected.

*Proposal No. 3:* The proposal to approve the amendment to Indevus Restated Certificate of Incorporation requires the affirmative vote of both (i) a majority of the total number of votes of Indevus common stock and preferred stock outstanding and entitled to vote, voting together as a single class (regardless of whether such holders are present in person or represented by proxy at the annual and special meeting) and (ii) the holders of a majority of the outstanding shares of Indevus common stock, voting separately as a class. With respect to this proposal, there will be no broker non-votes because brokerage firms may vote in their discretion on behalf of clients on this proposal even if such clients have not furnished voting instructions with respect to this proposal. Failures to vote and abstentions will be the equivalent of a vote against the proposal. Each of the votes specified above is required for the approval of the amendment to Indevus Restated Certificate of Incorporation. For example, if the affirmative vote of holders of a majority of the outstanding shares of common stock voting separately as a class were not obtained, then the amendment to Indevus Restated Certificate of Incorporation would not be approved by the required vote of the stockholders of the Company and the Restated Certificate of Incorporation would not be amended.

*Proposal Nos. 4, 5, 6 and 7:* The proposals to approve the amendments to the 2004 Equity Incentive Plan and the 1995 Employee Stock Purchase Plan and the proposal to ratify the appointment of PricewaterhouseCoopers LLP as Indevus independent registered public accounting firm each require the affirmative vote of a majority of the total number votes cast on the particular proposal (with Indevus common stock and preferred stock voting together as a single class). With respect to the plan amendments, abstentions and broker non-votes will have no effect on the outcome of the proposal. With respect to the ratification of the appointment of the independent registered accounting firm, there will be no broker non-votes because brokerage firms may vote in their discretion on behalf of clients on this proposal even if such clients have not furnished voting instructions with respect to this proposal and abstentions will have no effect on the outcome of this proposal.

As of the close of business on the record date for the annual and special meeting, the directors and executive officers of Indevus collectively beneficially owned approximately 8,742,264 shares of Indevus common stock inclusive of shares subject to stock options that may be exercised within 60 days following that date. Such shares represented approximately 13.48% of the total Indevus voting power as of such date.

As of the close of business on the record date for the annual and special meeting and the date of this joint proxy statement/prospectus, neither Indevus nor any of its directors or officers owned any shares of Valera

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common stock and neither Valera nor any of its directors or executive officers owned any shares of Indevus common stock.

#### How to Vote Your Shares

If you are a stockholder of Indevus and your shares are registered directly in your name, you may vote:

**By Internet.** You can submit a proxy via the internet until 11:59 Eastern Daylight Time on April 16, 2007 by accessing **www.voteproxy.com** and following the on-screen instructions. Have your proxy card available when you access the web page. Internet proxy submission is available 24 hours a day.

**By Telephone.** You can submit a proxy for your shares by telephone until 11:59 Eastern Daylight Time on April 16, 2007 by calling toll-free **1-800-PROXIES** from any touch-tone telephone and following the instructions. Have your proxy card available when you call. Telephone proxy submission is available 24 hours a day.

By Mail. Complete and mail the enclosed proxy card in the enclosed postage prepaid envelope to American Stock Transfer and Trust Company.

**In Person at the Meeting.** If you attend the meeting, you may deliver your completed proxy card in person or you may vote by completing a ballot, which will be available at the meeting.

By casting your vote by proxy, you are authorizing the individuals listed on the proxy to vote your shares in accordance with your instructions. If you sign and return the enclosed proxy card but do not specify how you want your shares voted, they will be voted FOR each of the proposals.

If your shares of Indevus common stock are held in street name (held for your account by a broker or other nominee):

By Mail. You will receive instructions from your broker or other nominee explaining how to vote your shares. Please follow their instructions carefully.

In Person at the Meeting. Contact the broker or other nominee who holds your shares to request a broker s proxy card and present that broker s proxy card and proof of identification at the meeting. Proxies; Counting Your Vote

All proxies received by Indevus prior to the annual and special meeting that are not revoked will be voted at the annual and special meeting in accordance with your instructions. If you hold shares in your name and sign, date and mail your proxy card without indicating how you want to vote, your shares will be voted as follows:

FOR approval of the issuance of Indevus common stock and CSRs pursuant to the merger agreement;

FOR the election of each of the nominees as directors;

FOR approval of the amendment to the restated certificate of incorporation;

FOR approval of both of the amendments to the 2004 Equity Incentive Plan;

FOR approval of the amendment to the 2005 Employee Stock Purchase Plan; and

FOR the ratification of the appointment of PricewaterhouseCoopers LLP as Indevus independent registered public accounting firm. Indevus board of directors does not presently intend to bring any other business before the annual and special meeting and is unaware of any matters, other than as set forth above, that may properly come before the annual and special meeting. If any other matters may properly come before the annual and special meeting, the persons named as proxies in the accompanying Indevus proxy, or their duly constituted substitutes acting at the annual and special meeting or any adjournment or postponement of the annual and special meeting, will be deemed authorized to vote or otherwise act on such matters in accordance with their judgment.

The persons named in the enclosed proxy, or their duly constituted substitutes acting at the annual and special meeting or any adjournment or postponement of the annual and special meeting, may propose and vote for one or more adjournments or postponements of the annual and special meeting, including adjournments or postponements to permit further solicitations of proxies sufficient to approve the issuance of Indevus common stock and CSRs pursuant to the merger agreement. No proxy voted against the proposal to approve the issuance of Indevus common stock and CSRs pursuant to the merger agreement will be voted in favor of any adjournment or postponement to permit further solicitation of proxies. Proxies solicited may be voted only at the annual and special meeting and any adjournment or postponement of the annual and special meeting and will not be used for any other Indevus meeting of stockholders.

Indevus transfer agent, American Stock Transfer & Trust Company, will serve as proxy tabulator and count the votes. The results will be certified by the inspectors of election.

### How to Change Your Vote

An Indevus stockholder who has given a proxy may revoke it at any time before it is exercised at the annual and special meeting by:

delivering to the Secretary of Indevus, a written notice, bearing a date later than the date of the proxy, stating that the proxy is revoked;

submitting a proxy at a later date by telephone or via the Internet, or by signing and delivering a proxy card relating to the same shares and bearing a later date than the date of the previous proxy prior to the vote at the annual and special meeting, in which case your later-submitted proxy will be recorded and your earlier proxy revoked; or

attending the annual and special meeting and voting in person (your attendance at the annual and special meeting, in and of itself, will not revoke the proxy).

Any written notice of revocation, or later dated proxy, should be delivered to:

Indevus Pharmaceuticals, Inc.

33 Hayden Avenue

Lexington, MA 02421

Attention: Secretary

Alternatively, you may hand deliver a written revocation notice, or a later dated proxy, to the Secretary at the annual and special meeting before voting begins.

If your shares of Indevus common stock are held by a bank, broker or other nominee, you must follow the instructions provided by the bank, broker or other nominee if you wish to change your vote.

#### Solicitation of Proxies and Expenses

The Indevus proxy accompanying this joint proxy statement/prospectus is solicited on behalf of Indevus board of directors. Indevus and Valera will share the costs, other than fees of accountants and attorneys, of preparing and mailing this joint proxy statement/prospectus, and Indevus will bear the other costs of the solicitation of proxies from its stockholders. Following the mailing of this joint proxy statement/prospectus, the directors, officers, employees and agents of Indevus and Valera and their respective subsidiaries may solicit proxies in person, by mail, or by telephone, facsimile or other electronic methods without additional compensation other than reimbursement for their actual expenses.

Indevus has retained a proxy solicitation firm, The Altman Group, to aid in the solicitation of proxies. Indevus will pay that firm an estimated fee of \$12,000, plus customary additional payment for telephone

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solicitations and reimbursement of expenses. In addition, brokerage houses and other custodians, nominees and fiduciaries will send beneficial owners the proxy materials. Indevus will, upon request, reimburse those brokerage houses and custodians for their reasonable expenses. **Indevus urges its stockholders to vote without delay.** 

### Householding of Annual and Special Meeting Materials

Some banks, brokers and other record holders may be participating in the practice of householding proxy statements. This means that only one copy of the proxy statement/prospectus may have been sent to multiple stockholders in your household. Indevus will promptly deliver a separate copy of the joint proxy statement/prospectus to you if you write to or call Indevus at the following address or phone number: Indevus Pharmaceuticals, Inc., 33 Hayden Avenue, Lexington, Massachusetts 02421, Telephone: (781) 861-8444, Attention: Investor Relations.

### **Recommendation of the Indevus Board of Directors**

Indevus board of directors has voted unanimously to approve the merger agreement and the issuance of Indevus common stock and contingent stock rights in the merger and believes that the merger is fair to, and in the best interests of, Indevus. **Indevus board of directors unanimously recommends that Indevus stockholders vote FOR approval of the issuance of Indevus common stock and contingent stock rights in the merger.** 

Indevus board of directors has also voted unanimously to approve the amendments to the Restated Certificate of Incorporation, the 2004 Equity Incentive Plan, and the 2005 Employee Stock Purchase Plan, and the audit committee of Indevus board of directors voted unanimously to appoint PricewaterhouseCoopers LLP as Indevus independent registered public accounting firm. Indevus board of directors unanimously recommends that Indevus stockholders vote FOR approval of the amendments to the Restated Certificate of Incorporation, the 2004 Equity Incentive Plan, and the 2005 Employee Stock Purchase Plan, and FOR ratification of the appointment of PricewaterhouseCoopers LLP.

### THE VALERA SPECIAL MEETING

Valera is furnishing this document to holders of Valera common stock in connection with the solicitation by Valera s board of directors of proxies to be voted at the special meeting of Valera stockholders to be held on April 17, 2007, and at any adjournment or postponement of the meeting.

This document is first being mailed to Valera stockholders on or about March 14, 2007. This document is also furnished to Valera stockholders as a prospectus in connection with the issuance by Indevus of shares of Indevus common stock and contingent stock rights as contemplated by the merger agreement.

### Date, Time and Place of Meeting

The special meeting will be held on April 17, 2007 at 10:00 a.m., local time, at Valera s offices at 7 Clark Drive, Cranbury, NJ 08512.

### **Purpose of the Special Meeting**

The purpose of the Valera special meeting is to consider and vote on the following proposal:

To adopt the Agreement and Plan of Merger, dated as of December 11, 2006, by and among Indevus, Merger Sub (which is a wholly-owned subsidiary of Indevus) and Valera, a copy of which is included as *Annex A* to this joint proxy statement/prospectus. Valera stockholders also will be asked to transact any other business that may be properly brought before the special meeting or any adjournments or postponements of the special meeting. At this time, Valera s board of directors is unaware of any matters, other than the proposal set forth above, that may properly come before the special meeting.

### **Record Date; Shares Outstanding and Entitled to Vote**

Valera has fixed the close of business on March 12, 2007, as the record date for the determination of holders of Valera common stock, par value, \$0.001 per share, entitled to notice of, and to vote on all matters at, the special meeting and any adjournment or postponement of the special meeting. In deciding all matters that come before the special meeting, each holder of Valera common stock is entitled to one vote per share of Valera common stock held as of the close of business on the record date.

At the close of business on the record date for the special meeting, there were outstanding and entitled to vote 14,985,670 shares of Valera common stock, held by approximately 16 holders of record. There are no other shares of Valera capital stock entitled to notice of and to vote at the special meeting. Accordingly, the aggregate number of votes of Valera common stock that may be cast at the special meeting for all matters is 14,985,670.

### Quorum; Abstentions and Broker Non-Votes

A quorum, consisting of 7,492,836 shares, which is a majority of the outstanding shares of Valera common stock entitled to vote, must be represented at the special meeting in person or by proxy before any action may be taken with respect to the adoption of the merger agreement or any other matters at the special meeting. Abstentions and broker non-votes will be counted as shares that are present and entitled to vote for purposes of determining the presence of a quorum.

An abstention occurs when a stockholder sends in a proxy with explicit instructions to decline to vote regarding a particular matter. Broker non-votes are shares held by brokers or nominees for which voting instructions have not been received from the beneficial owners or the persons entitled to vote those shares and the broker or nominee does not have discretionary voting power under rules applicable to broker-dealers. If you hold

your shares of Valera common stock through a broker, bank or other nominee, generally the nominee may only vote your shares in accordance with your instructions. However, if your broker, bank or other nominee has not timely received your instructions, it may vote on matters for which it has discretionary voting authority. Under rules applicable to broker-dealers, the proposal to adopt the merger agreement is not a matter on which brokerage firms may vote in their discretion on behalf of their clients if such clients have not furnished voting instructions within ten days of the special meeting. If you do not instruct your broker, bank or other nominee, they will not be able to vote your shares.

Because adoption of the merger agreement requires the affirmative vote of a majority of the shares of Valera common stock outstanding on the record date and entitled to vote, abstentions and broker non-votes will have the same effect as votes against adoption of the merger agreement. In addition, the failure of a Valera stockholder to return a proxy will have the effect of a vote against the adoption of the merger agreement. Accordingly, if a broker or bank holds your shares you are urged to instruct your broker or bank on how to vote, it will have the effect of a vote against adoption of the merger agreement.

### **Vote Required**

Adoption of the merger agreement by Valera s stockholders is required by Delaware law. The affirmative vote of the holders of a majority of the shares of Valera common stock outstanding on the record date and entitled to vote at the special meeting is required to adopt the merger agreement.

At the close of business on the record date for the special meeting, the directors and executive officers of Valera collectively beneficially owned approximately 9,093,070 shares of Valera common stock or approximately 58% of the outstanding shares of Valera common stock (inclusive of shares subject to stock options that may be exercised within 60 days following that date).

In connection with the execution of the merger agreement, two Valera stockholders entered into voting agreements with Indevus: affiliates of Sanders Morris Harris, Inc., or SMH, and Psilos Group Partners II-S, L.P., or Psilos. As of the record date for the Valera special meeting, SMH and Psilos were the record and/or beneficial owners, respectively, of 5,449,980 and 728,037 shares of Valera common stock. Such shares represent approximately 36.37% and 4.86%, respectively, and approximately 41.23% in the aggregate, of Valera s outstanding shares of common stock as of the record date. Pursuant to these voting agreements these stockholders have agreed, among other things and subject to limited exceptions, to vote all their Valera shares in favor of adoption of the merger agreement. James C. Gale, our chairman of the board, is a managing director of SMH. Jeffrey M. Krauss, a member of our board of directors, is affiliated with Psilos.

At the close of business on the record date for the special meeting and the date of this joint proxy statement/prospectus, neither Valera nor any of its directors or executive officers owned any shares of Indevus common stock and neither Indevus nor any of its directors or officers owned any shares of Valera common stock.

### How to Vote Your Shares

If you are a stockholder of Valera and your shares are registered directly in your name, you may vote:

**By Internet.** Access **www.proxyvote.com** and follow the on-screen instructions. Have your proxy card available when you access the web page.

By Telephone. Call toll-free **1-800-690-6903** from any touch-tone telephone and follow the instructions. Have your proxy card available when you call.

**By Mail.** Complete and mail the enclosed proxy card in the enclosed postage prepaid envelope to ADP Investor Communication Services. By casting your vote by proxy, you are authorizing the individuals listed on the proxy to vote your shares in accordance with your instructions. If you sign and return the enclosed proxy but do not specify how you want your shares voted, they will be voted FOR the proposal to adopt the merger agreement.

**In Person at the Meeting.** If you attend the meeting, you may deliver your completed proxy card in person or you may vote by completing a ballot, which will be available at the meeting.

If your shares of Valera common stock are held in street name (held for your account by a broker or other nominee):

By Mail. You will receive instructions from your broker or other nominee explaining how to vote your shares. Please follow their instructions carefully.

In Person at the Meeting. Contact the broker or other nominee who holds your shares to request a broker s proxy card and present that broker s proxy card and proof of identification at the meeting. Proxies; Counting Your Vote

All proxies received by Valera prior to the special meeting that are not revoked will be voted at the special meeting in accordance with the instructions indicated on the proxies. If you hold shares in your name and sign, date and mail your proxy card without indicating how you want to vote, your shares will be voted FOR adoption of the merger agreement.

Valera s board of directors does not presently intend to bring any other business before the special meeting and is unaware of any matters, other than the proposal to adopt the merger agreement that may properly come before the special meeting. If any other matters may properly come before the special meeting, the persons named as proxies in the accompanying Valera proxy, or their duly constituted substitutes acting at the special meeting or any adjournment or postponement of the special meeting, will be deemed authorized to vote or otherwise act on such matters in accordance with their judgment.

The persons named in the enclosed proxy, or their duly constituted substitutes acting at the special meeting or any adjournment or postponement of the special meeting, may propose and vote for one or more adjournments or postponements of the special meeting, including adjournments or postponements to permit further solicitations of proxies sufficient to adopt the merger agreement. No proxy voted against the proposal to adopt the merger agreement will be voted in favor of any adjournment or postponement to permit further solicitation of proxies solicited may be voted only at the special meeting and any adjournment or postponement of the special meeting and will not be used for any other Valera meeting of stockholders.

ADP Investor Communication Services, will serve as proxy tabulator and count the votes. The results will be certified by the inspectors of election.

### How to Change Your Vote

A Valera stockholder who has given a proxy may revoke it at any time before it is exercised at the special meeting by:

delivering to the Secretary of Valera, a written notice, bearing a date later than the date of the proxy, stating that the proxy is revoked;

submitting a proxy at a later date by telephone or via the Internet, or by signing and delivering a proxy card relating to the same shares and bearing a later date than the date of the previous proxy prior to the vote at the special meeting, in which case your later-submitted proxy will be recorded and your earlier proxy revoked; or

attending the special meeting and voting in person (your attendance at the special meeting, in and of itself, will not revoke the proxy).

Any written notice of revocation, or later dated proxy, should be delivered to:

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Valera Pharmaceuticals, Inc.

7 Clarke Drive

Cranbury, New Jersey 08512

Attention: Corporate Secretary

Alternatively, you may hand deliver a written revocation notice, or a later dated proxy, to the Secretary at the special meeting before voting begins.

If your shares of Valera common stock are held by a bank, broker or other nominee, you must follow the instructions provided by the bank, broker or other nominee if you wish to change your vote.

### Solicitation of Proxies and Expenses

The Valera proxy accompanying this joint proxy statement/prospectus is solicited on behalf of Valera's board of directors. Valera and Indevus will share the costs, other than fees of accountants and attorneys, of preparing and mailing this joint proxy statement/prospectus, and Valera will bear the other costs of the solicitation of proxies from its stockholders. Following the mailing of this joint proxy statement/prospectus, the directors, officers, employees and agents of Valera and Indevus and their respective subsidiaries may solicit proxies in person, by mail, or by telephone, facsimile or other electronic methods without additional compensation other than reimbursement for their actual expenses.

Brokerage houses and other custodians, nominees and fiduciaries will send beneficial owners the proxy materials. Valera will, upon request, reimburse those brokerage houses and custodians for their reasonable expenses. **Valera urges its stockholders to vote without delay.** 

### Householding of Special Meeting Materials

Some banks, brokers and other record holders may be participating in the practice of householding proxy statements. This means that only one copy of the proxy statement/prospectus may have been sent to multiple stockholders in your household. Valera will promptly deliver a separate copy of the joint proxy statement/prospectus to you if you write to or call Valera at the following address or phone number: Valera Pharmaceuticals, Inc., 7 Clarke Drive, Cranbury, New Jersey 08512, Telephone: (609) 235-3000, Attention: Corporate Secretary.

### **Recommendation of the Valera Board of Directors**

Valera s board of directors has unanimously approved the merger agreement and has determined that the merger agreement and the merger are advisable and fair to, and in the best interests of, Valera s stockholders. Valera s board of directors unanimously recommends that Valera stockholders vote FOR adoption of the merger agreement.

### THE MERGER

### **Background of the Merger**

The board of directors and senior management of Indevus regularly discuss Indevus business and strategic direction including the goals of maximizing the value of Indevus current product portfolio and urology franchise as well as evaluating growth opportunities most likely to promote stockholder value. In recent years, Indevus has sought to leverage its investment in commercialization and sales and marketing resources through inlicense, co-promotion or acquisition of additional drugs and drug candidates, primarily focusing on urology, and product life-cycle management. Valera s board of directors and senior management engaged in similar discussions and strategic planning.

In October 2004, Valera launched Vantas in the United States. Following this launch, in December 2004, representatives of Indevus contacted representatives of Valera to discuss a potential co-promotion arrangement with Valera to supplement Valera s sales and marketing of Vantas. On January 11, 2005, certain Indevus personnel met with representatives of Valera in Newark, New Jersey to discuss the potential co-promotion arrangement in further detail. On January 14, 2005, Valera and Indevus signed a mutual confidential nondisclosure agreement in order to learn more about each other s operations and future opportunities.

On February 1, 2005, Dr. Glenn Cooper, Chief Executive Officer and Chairman of Indevus, and Dr. David Tierney, President and Chief Executive Officer of Valera, met in New York City to discuss potential opportunities between the companies. Following this meeting, no additional discussions occurred with regard to any such opportunities until December 2005.

In March 2005, Valera filed its initial registration statement with the SEC in connection with Valera s initial public offering. Valera completed its initial public offering in February 2006.

During the second half of 2005, in the context of reviewing various strategic alternatives, Valera s board and management considered the benefits of potential strategic combinations and were assisted by UBS and Banc of America Securities in identifying potential parties with which Valera could consider entering into a strategic transaction. Valera management engaged in some preliminary discussions with various parties, including Indevus, regarding a potential strategic transaction. On December 19, 2005, Indevus management, including Dr. Cooper, met with Valera s management at Valera s headquarters in Cranbury, New Jersey to resume discussions on the two companies and business generally. Following this meeting, no additional substantive discussions occurred until July 2006.

In July 2006, Valera s Vice President of Business Development contacted Indevus Chief Business Officer to restart discussions regarding a potential co-promotion opportunity for Vantas. Following this meeting, Indevus management discussed the co-promotion opportunity internally and decided to pursue the opportunity.

On August 14, 2006, Indevus personnel met with certain Valera personnel at Valera s headquarters in Cranbury, New Jersey. The parties discussed the potential co-promotion of Vantas and additional strategic opportunities.

On August 23, 2006, certain representatives of Indevus presented a proposal regarding the co-promotion arrangement to certain representatives of Valera. A representative of Valera noted that Valera s board of directors had an upcoming meeting the following month and that Valera would want to be able to make a recommendation of a potential co-promotion at that time.

On August 25, 2006, Indevus sent a non-binding term sheet regarding a potential co-promotion to Valera. On August 30, 2006, representatives of Indevus met via telephone with representatives of Valera to discuss the term sheet, and after the discussions, Valera s representatives advised Indevus representatives that Valera would submit the co-promotion proposal to its board of directors at its September board meeting.

At the regular meeting of Valera's board of directors on September 6, 2006, Valera's board discussed the Indevus proposed co-promotion terms. Following the board meeting, Valera communicated its board's opposition to the proposed terms to Indevus.

On September 12, 2006, Indevus board of directors held its regular meeting. During this meeting, Indevus senior management and board of directors discussed the opportunity to co-promote Vantas. The Indevus board discussed the advantages of a co-promotion arrangement with Valera, including potential synergies between the Indevus and Valera sales forces. The Indevus board also discussed the possibility of expanding the discussions with Valera to include an acquisition of Valera's assets and considered Valera's product portfolio and manufacturing and supply capabilities.

Throughout the remainder of September 2006, Dr. Cooper and James C. Gale, the chairman of Valera s board of directors, had various discussions regarding a strategic transaction in addition to the co-promotion arrangement. On September 26, 2006, Dr. Cooper and Mr. Gale met in New York City to discuss a potential strategic transaction.

At a special meeting of Indevus board held on October 2, 2006, Indevus management noted that, as a result of ongoing discussions between Valera and Indevus regarding co-promotion arrangements, the two companies had begun to discuss a potential strategic transaction. Indevus board discussed generally the potential terms of a strategic transaction, as well as Valera's manufacturing capabilities and the products and product candidates of strategic interest to Indevus.

At a special meeting of Valera's board on October 16, 2006, Valera's board discussed the status of the discussions concerning the possible strategic transaction with Indevus. Valera's board also discussed the fact that, given its familiarity with Valera and Indevus, UBS had been requested to assist both companies in their initial discussions concerning a possible strategic transaction. Following this meeting, Valera, Indevus and UBS agreed that, in the event that Valera and Indevus decided to proceed with a potential strategic transaction, UBS would provide financial advisory services only to Indevus and that Banc of America Securities would continue to provide financial advisory services to Valera in connection with such transaction.

On October 18, 19 and 20, Valera made a presentation regarding its business to Indevus and its advisors and Indevus performed due diligence related activities.

During the week of October 23, 2006, Indevus made a presentation regarding its business to Valera and its advisors and Valera performed due diligence related activities.

During the following weeks, Indevus and Valera each authorized its respective management team and external advisors to continue to exchange due diligence information and engage in discussions regarding a strategic transaction and a co-promotion arrangement. Draft term sheets were exchanged that served as the basis for these discussions.

At a special meeting of Indevus board held on November 2, 2006, the board discussed the progress of due diligence regarding Valera, its financial results and product portfolio and also had discussions regarding a co-promotion arrangement with Valera and a potential business combination transaction.

On November 22, 2006, Skadden, Arps, Slate, Meagher & Flom LLP, legal counsel for Indevus, sent a draft merger agreement to Valera and Pepper Hamilton LLP, Valera s legal counsel, for review. Over the course of the ensuing week, Indevus management and Valera management continued to engage in discussions concerning a possible merger, as well as a possible co-promotion arrangement.

At a special meeting of Indevus board held on November 27, 2006, Indevus management updated the board on the status of the proposed merger. Various management representatives provided detailed overviews of the merger negotiations and due diligence process and findings, highlighting the material terms of the draft merger agreement, including the consideration proposed to be paid to Valera stockholders. Management representatives also provided a detailed overview of Valera s product portfolio and presented a financial review

and analysis of the transaction. Indevus financial advisor discussed with the board at this meeting the types of financial analyses that it would expect to perform in evaluating the merger consideration from a financial point of view. At this meeting, Indevus board of directors evaluated and discussed the merits of proceeding with the proposed merger and authorized management to continue moving forward with the negotiations.

On November 30, 2006, Valera s board of directors held a conference call to discuss the status of the merger negotiations, as well as review the material terms of the proposed transaction and the status of the due diligence investigations.

On December 1, 2006, Valera's legal counsel provided a revised draft merger agreement to Indevus' legal counsel. Between December 1, 2006 and December 11, 2006, the parties' respective management teams and legal and financial advisors held numerous discussions to complete their due diligence and to finalize the terms of the merger agreement and related documents.

On December 5, 2006, Indevus board held its regular meeting At this meeting, Indevus senior management and its legal and financial advisors updated the board on the status of the proposed merger. Indevus legal advisors reviewed the terms and current status of the draft merger agreement and related agreements. Management representatives provided additional information relating to Valera, the integration plan and management s financial review and analysis of the transaction. At this meeting, Indevus financial advisor also discussed with the directors financial aspects of the proposed transaction. Indevus senior management also provided an update on negotiations relating to a co-promotion arrangement. At this meeting, Indevus board of directors engaged in a general discussion relating to the advisability of the proposed merger and authorized management to continue moving forward with the negotiations.

On December 7, 2006, Valera's board of directors held a regular meeting, which was also attended by Valera's senior management, Banc of America Securities, and Valera's outside legal counsel. At this meeting, Valera's senior management and outside legal counsel provided updates regarding the ongoing due diligence and the terms of the proposed merger agreement and related agreements. Valera's financial advisor also reviewed with Valera's board of directors its preliminary financial analysis of the merger consideration. Valera's board of directors continued to express their continued support for the proposed merger with Indevus.

On December 11, 2006, Valera's board of directors held a special meeting by telephone to consider the proposed transaction. Valera's senior management, Banc of America Securities and Valera's outside legal counsel also attended this meeting. Valera's senior management reviewed with the board of directors the strategic considerations relating to the transaction, as well as the progress of the negotiations regarding the terms of the transaction. Valera's management also informed the board of the results of its due diligence review of Indevus. Additionally, Banc of America Securities, after reviewing with Valera's board of directors its financial analysis of the merger consideration, delivered to the Valera board an oral opinion, which was confirmed by delivery of a written opinion dated December 11, 2006, to the effect that, as of that date and based on and subject to various assumptions, matters considered and limitations described in its opinion, the merger consideration to be received by holders of Valera common stock (other than certain stockholders of Valera who were entering into voting agreements in connection with the merger) was fair, from a financial point of view, to such holders. During these discussions, Valera's board discussed the proposed transaction and related agreements. Following further review and discussion, the directors present voted unanimously to approve the merger and the transactions contemplated by the merger agreement and to approve and adopt the merger agreement and resolved to recommend that Valera stockholders vote to adopt the merger agreement. The one Valera director who was not at the meeting subsequently approved and ratified these actions of the board.

On the evening of December 11, 2006, Indevus board held a special meeting to consider and take action on the proposed transaction. Indevus senior management and legal and financial advisors provided updates

regarding the final terms of the proposed merger agreement and related agreements and the final terms of a co-promotion agreement. Also at this meeting, UBS reviewed with Indevus board of directors its financial analysis of the merger consideration and rendered to Indevus board of directors an oral opinion, which opinion was confirmed by delivery of a written opinion dated December 11, 2006, to the effect that, as of that date and based on and subject to various assumptions, matters considered and limitations described in its opinion, the merger consideration (defined as (i) the number of shares of Indevus common stock equal to the quotient of \$7.75 divided by the Indevus Common Stock Value and (ii) the CSRs) to be paid by Indevus was fair, from a financial point of view, to Indevus. Following deliberations, Indevus board of directors unanimously approved the merger agreement and the related agreements and the transactions contemplated by those agreements, and resolved to recommend that its stockholders vote to approve the issuance of shares of Indevus company stock and contingent stock rights in the merger. The Indevus board also approved the Vantas co-promotion agreement with Valera.

The parties conveyed the results of their respective meetings to the other. Thereafter, the parties executed the merger agreement as well as the Vantas co-promotion agreement and Indevus, SMH and Psilos executed the voting agreements. Indevus and Valera announced the transaction in a joint press release issued the morning of December 12, 2006.

### Indevus Reasons for the Merger

The primary rationale behind the Indevus board s approval of the merger was to further Indevus goal of becoming a leading specialty pharmaceutical company focused on urology and endocrinology. The merger represents a combination of assets with a strategic fit that is expected to accelerate both companies strategic initiatives, driving future profitable growth and building long term value. Central to that primary rationale, there were several important factors that contributed to the Indevus board s approval, including the following:

### Furtherance of Corporate Strategy and Utilization of Sales Force

The merger and combination of the companies is a good fit with Indevus corporate strategy of building a world class urology and endocrinology franchise. The merger will also leverage Indevus national sales force.

#### Growing proprietary product portfolio and pipeline

The companies have complementary product lines focused on urology and endocrinology. The addition of the current and future revenue from Valera's products and product candidates, including Vantas, Supprelin-LA, Valstar, the ureteral stent and VP003 (Octreotide implant), if approved, will diversify and strengthen Indevus revenue base, thereby reducing the business risk of being heavily dependent on a limited number of products.

#### Combination of core human resources and competencies

The complementary nature of the development, manufacturing, and sales and marketing competencies of the Valera and Indevus employees and the belief that the combined workforce, particularly in the areas of sales and marketing, would yield a more fully integrated, effective and competitive specialty pharmaceutical company.

#### **Financial implications**

The combination of the two companies should allow the combined company to achieve its strategic objectives, with increased revenue, efficiencies in operating expenses and an enhanced ability to pursue strategic opportunities and more favorable financing alternatives, if needed.

In evaluating the merger, Indevus board consulted with Indevus management and legal and financial advisors. In addition, Indevus board considered the following additional factors, all of which it viewed as supporting its decision to approve the merger and the rationale for the merger outlined above:

historical financial information concerning Indevus and Valera;

Indevus and Valera s respective historical stock performance;

the results of the due diligence review of Valera s businesses and operation;

the assessment that the proposed merger was likely to meet each of the criteria they deemed necessary for a successful merger strategic and cultural fit, acceptable execution risk and financial benefits to Indevus and Indevus stockholders;

the current and prospective competitive environment in which Indevus operates, including the likely effect of that competitive environment on Indevus in light of, and in the absence of, the proposed merger;

alternative strategies, including the status quo and other possible acquisition candidates considered over a period of more than a year, and the resulting determination that the acquisition of Valera was a good strategic fit and presented a unique opportunity to bring together two companies with synergistic strategies and complementary skills and assets;

the terms and conditions of the merger agreement, including the fact that the merger agreement is not subject to termination as a result of any change in the trading prices of either company s stock between signing of the merger agreement and closing;

the determination that an exchange ratio that is collared is appropriate to reflect the strategic purpose of the merger and consistent with market practice for mergers of this type, and provides a degree of certainty as to the respective ownership interests of the Indevus and Valera stockholders based on fundamental valuation assessments and avoids significant fluctuations caused by short-term market volatility;

the opinion of Indevus financial advisor, including its financial presentation, dated December 11, 2006, to Indevus board of directors as to the fairness, from a financial point of view and as of the date of the opinion, to Indevus of the merger consideration (defined as (i) the number of shares of Indevus common stock equal to the quotient of \$7.75 divided by the Indevus Common Stock Value and (ii) the CSRs) to be paid by Indevus, as more fully described below under the caption The Merger Opinion of Indevus Financial Advisor ;

the likelihood that the merger will be completed, including the likelihood that the merger will receive all necessary regulatory approvals without unacceptable conditions; and

the expected qualification of the transaction as a reorganization for U.S. federal income tax purposes, which was considered beneficial compared to alternative, taxable structures because it generally would enable Valera stockholders to defer U.S. federal income tax on the gain in their Valera stock to the extent they received Indevus stock in the merger.

Indevus board of directors also considered the potential negative factors and risks of the merger and potential conflicts of interest, including the following:

the risk that the potential benefits sought in the merger, including those outlined above, might not be realized;

the risk that a failure of Valera s products to meet development, regulatory and commercialization goals forecast by Indevus could prevent Indevus from achieving its financial objectives related to profitability and earnings growth;

the possibility that Indevus share price might fall following announcement of the transaction due to arbitrageurs sales of Indevus stock in conjunction with hedging strategies designed to lock in the premium offered by Indevus in the merger;

the risk that key Valera personnel might choose not to remain employed by Indevus following the merger, particularly in light of the fact that outstanding Valera options will be cancelled when the merger is completed;

the possibility that the merger might not be completed or might be unduly delayed;

the increased need for additional capital to support the costs involved in completing the merger and Valera s operations;

other risks that could adversely impact the future financial performance of Valera including inadequate intellectual property coverage, adverse competitive or other market conditions that could negatively impact demand for or sales of Vantas, and the delay or denial of regulatory or marketing approval or patent coverage for Supprelin-LA, Valera s ureteral stent, VP003 (Octreotide implant) and Valstar; and

the time, effort and costs involved in combining the two businesses, including the risk of diverting management s attention from other strategic priorities to implement merger integration efforts.

In view of the wide variety of factors considered in connection with its evaluation of the merger and the complexity of these matters, Indevus board did not find it useful, and did not attempt, to quantify, rank or otherwise assign relative weights to these factors. In considering the factors described above, individual members of Indevus board may have given different weight to different factors. The Indevus board conducted an overall evaluation of the factors described above and considered the factors overall to be favorable to, and to support, its determination. This explanation of the Indevus board s reasoning and much of the other information presented in this section is forward-looking in nature and, therefore, should be read in light of the factors discussed under the heading Information Regarding Forward-Looking Statements beginning on page 68 of this joint proxy statement/prospectus.

The Indevus board of directors unanimously determined that the merger, the merger agreement and the transactions contemplated by the merger agreement, including the issuance of shares of Indevus common stock and contingent stock rights to Valera stockholders, are advisable and in the best interests of Indevus and its stockholders and unanimously approved the merger agreement and those transactions.

The Indevus board unanimously recommends that Indevus stockholders vote FOR approving the issuance of shares of Indevus common stock and contingent stock rights to Valera stockholders pursuant to the merger agreement.

#### Valera s Reasons for the Merger

In reaching its decision to approve the merger, Valera s board consulted with Valera s management and Valera s legal and financial advisors, and considered the following potentially positive factors:

Valera s board s belief that the combination of the businesses of Valera and Indevus would result in an organization with greater commercial and marketing resources to have a more significant presence in the urology and endocrinology fields, including increased sales volume of Vantas resulting from the larger sales force and the corresponding increased sales revenue;

Valera s board s belief that the combination of the businesses of Valera and Indevus would result in an organization with greater financial, technical and other resources for a significant acceleration in the commercial success of the combined company s commercial and pipeline products, and therefore a greater ability to support research and development of Valera s product pipeline;

the opportunity of affiliating with a company such as Indevus with attractive pipeline and product prospects;

Valera s difficulties in competing against larger companies with greater resources;

the opportunity the transaction affords Valera s stockholders to reduce their exposure to the risks inherent in Valera s current reliance on a single marketed product;

the opportunity to reduce the volatility associated with Valera s common stock;

the fact that the transaction would allow Valera s stockholders to receive an equity interest in Indevus and thereby continue to participate in the potential success of Valera s current product pipeline;

the structure of the transaction would allow Valera s stockholders to directly benefit, through the contingent stock rights, from the potential success of Valera s current product pipeline;

the expected tax treatment for Valera s stockholders of the exchange of Valera common stock for Indevus common stock;

the current and historical market prices of Valera s common stock relative to the \$9.81 per share implied total merger consideration, as calculated by Banc of America, and the fact that \$9.81 per share represented a 81% premium over the closing price of Valera s common stock on December 11, 2006 and a 88% premium to the average closing price of Valera s common stock over the 25 trading day period up to and including December 11, 2006.

a comparison of recent merger and acquisition transactions in the biotechnology industry as well as the trading performance for comparable companies in the specialty pharmaceutical industry;

Banc of America Securities financial presentation, including its opinion dated December 11, 2006, to Valera's board of directors as to the fairness, from a financial point of view and as of the date of the opinion, of the merger consideration, as more fully described below under the caption The Merger Opinion of Valera's Financial Advisor;

the terms of the merger agreement, including the parties respective representations, warranties and covenants and the conditions to closing;

the collar provision of the merger agreement, which affords protection against the risk of an increase in the market price of Indevus common stock above the upper end of the collar prior to the consummation of the transaction;

the reasonableness and reciprocal nature of the termination fee, taking into account the other terms of the merger agreement, especially the collar provision, and the range of commercially reasonable termination fees for a transaction of this size; and

the likelihood that the transaction will be consummated.

Valera s board of directors also identified and considered a variety of potentially negative factors in its deliberations concerning the merger, including, but not limited to:

the risk that Indevus product candidates would not be commercialized because of failure of clinical trials or adverse changes to the urology or endocrinology markets;

the risk that the potential benefits sought in the transaction might not be realized;

the collar provision of the merger agreement, which (1) limits the upside associated with an increase in the market price of Indevus common stock prior to the consummation of the transaction, unless the increase is above the upper end of the collar and (2) does not afford protection in the event of a decline in the market price of Indevus common stock below the lower end of the collar prior to consummation of the transaction;

the risk that the milestones set forth in the CSR agreements would not be achieved;

the difficulty of integrating the businesses of Valera and Indevus, and the possible adverse impact from senior management devoting significant time and effort on completing the transaction and integrating the two businesses;

the risk of increased competition, including competition from generic competitors;

the possibility that the transaction might not be completed and the potential adverse effect of the public announcement of the transaction on:

Valera s overall competitive position;

Valera s ability to attract and retain key management, sales, marketing and technical personnel;

Valera s collaborations and other key relationships;

the risk that Valera would be required to pay Indevus a significant break-up fee in the event either Valera or Indevus terminates the merger agreement under specified circumstances;

Valera s ability to consummate a strategic transaction in the future in the event the merger agreement is terminated; and

many of the risks described under Risk Factors beginning on page 34 of this proxy statement/prospectus. During its deliberations concerning the merger, Valera s board was also aware that some of Valera s executive officers, directors and employees have interests in the merger and have arrangements that are different from, or in addition to, those of Valera s stockholders generally, as described under The Merger Interests of Certain Persons in the Merger.

While Valera s board considered potentially negative and potentially positive factors, Valera s board concluded that, overall, the potentially positive factors outweighed the potentially negative factors.

The foregoing discussion summarizes the material information and factors considered by Valera's board in its consideration of the merger. Valera's board collectively reached the unanimous decision to approve the merger agreement in light of the factors described above and other factors that each member of the board felt were appropriate. In view of the wide variety of factors and the quality and amount of information considered, Valera's board did not find it useful or practicable to and did not make specific assessments of, quantify, rank or otherwise assign relative weights to the specific factors considered in reaching its determination. Individual members of Valera's board may have given different weight to different factors.

This explanation of the Valera board s reasoning and much of the other information presented in this section is forward-looking in nature and, therefore, should be read in light of the factors discussed under the heading Information Regarding Forward-Looking Statements on page 68 of this joint proxy statement/prospectus.

The Valera board of directors has unanimously approved the merger agreement and has determined that the merger agreement and the merger are advisable and fair to, and in the best interests of, Valera and its stockholders.

### The Valera board of directors recommends that Valera stockholders vote FOR adoption of the merger agreement.

### **Opinion of Indevus** Financial Advisor

On December 11, 2006, at a meeting of Indevus board of directors held to evaluate the proposed merger, UBS delivered to Indevus board of directors an oral opinion, which opinion was confirmed by delivery of a written opinion dated December 11, 2006, to the effect that, as of that date and based on and subject to various assumptions, procedures followed, matters considered and limitations described in its opinion, the merger consideration to be paid by Indevus was fair, from a financial point of view, to Indevus. For purposes of UBS opinion, the merger consideration refers to (i) the number of shares of Indevus common stock equal to the quotient of \$7.75 divided by the Indevus Common Stock Value and (ii) the CSRs.

The full text of UBS opinion describes the assumptions made, procedures followed, matters considered and limitations on the review undertaken by UBS. This opinion is attached as *Annex B* and is incorporated into this joint proxy statement/prospectus by reference. **UBS opinion is directed only to the fairness, from a financial point of view, to Indevus of the merger consideration to be paid by Indevus and does not address any other aspect of the merger. The opinion does not address the relative merits of the merger as compared to other business strategies or transactions that might be available to Indevus or Indevus underlying business decision to effect the merger. The opinion does not constitute a recommendation to any stockholder as to how such stockholder should vote or act with respect to the merger. Holders of Indevus common stock are encouraged to read this opinion carefully in its entirety.** The summary of UBS opinion described below is qualified in its entirety by reference to the full text of its opinion.

In arriving at its opinion, UBS:

reviewed publicly available business and financial information relating to Indevus and Valera;

reviewed internal financial information and other data relating to Valera s business and financial prospects that were provided to UBS by the managements of Valera and Indevus and not publicly available, including financial forecasts and estimates (inclusive of potential synergies) prepared by Indevus management with respect to Valera and the three Valera products in development to which the CSRs relate (including forecasts and estimates as to the timing and probability of achieving certain milestones with respect to the those products in development) after giving effect to the merger;

reviewed internal financial information and other data relating to Indevus business and financial prospects that were provided to UBS by Indevus management and not publicly available, including financial forecasts and estimates prepared by Indevus management;

considered pro forma effects of the merger on Indevus financial statements;

conducted discussions with members of the senior managements of Indevus and Valera concerning the businesses and financial prospects of Indevus and Valera;

reviewed publicly available financial and stock market data with respect to other companies UBS believed to be generally relevant;

compared the financial terms of the merger with the publicly available financial terms of other transactions UBS believed to be generally relevant;

reviewed current and historical market prices of Indevus common stock and Valera common stock;

reviewed the merger agreement and forms of the contingent stock rights agreements; and

conducted such other financial studies, analyses and investigations, and considered such other information, as UBS deemed necessary or appropriate.

In connection with its review, with Indevus consent, UBS did not assume any responsibility for independent verification of any of the information provided to or reviewed by UBS for the purpose of its opinion and, with Indevus consent, UBS relied on that information being complete and accurate in all material respects. In addition, with Indevus consent, UBS did not make any independent evaluation or appraisal of any of the assets or liabilities, contingent or otherwise, of Indevus or Valera, and was not furnished with any evaluation or appraisal. With respect to the financial forecasts and estimates including potential synergies, and pro forma effects referred to above, UBS assumed, at Indevus direction, that they were reasonably prepared on a basis reflecting the best currently available estimates and judgments of Indevus management as to the future performance of Indevus and Valera after giving effect to the merger and such pro forma effects. In addition, UBS assumed, with Indevus approval, that the financial forecasts and estimates (inclusive of potential synergies) referred to above would be achieved at the times and in the amounts projected. UBS relied, at Indevus direction, without independent verification or investigation, upon the assessments of Indevus management as to the products and product candidates of Indevus and Valera, including the three Valera products in development to which the CSRs relate, and the risks associated with such products and product candidates (including, without limitation, the potential impact of drug competition, the timing and probability of successful testing, development and marketing, and of approval by appropriate governmental authorities, of such products and product candidates and, accordingly, the timing and probability of the issuance of Indevus common stock pursuant to the CSRs). UBS also assumed, with Indevus consent, that the merger would qualify for U.S. federal income tax purposes as a

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reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended. UBS opinion was necessarily based on economic, monetary, market and other conditions as in effect on, and information made available to UBS as of, the date of its opinion.

At Indevus direction, UBS was not asked to, and it did not, offer any opinion as to the terms, other than the merger consideration to the extent expressly specified in UBS opinion, of the merger agreement and the

contingent stock rights agreements, including, without limitation, the fixed exchange ratios provided for in the merger if the Indevus Common Stock Value is greater than \$8.05 or less than \$6.59, or the form of the merger. UBS expressed no opinion as to what the value of Indevus common stock or any contingent stock right would be when issued in the merger or the prices at which Indevus common stock or Valera common stock would trade, or the value at which any contingent stock right might be transferable, at any time. In rendering its opinion, UBS assumed, with Indevus consent, that (i) the final executed forms of the contingent stock rights agreements would not differ in any material respect from the forms that UBS reviewed, (ii) Indevus, Merger Sub and Valera would comply with all material terms of the merger agreement and the contingent stock rights agreements and (iii) the merger would be consummated in accordance with the terms of the merger agreement and the contingent stock rights agreements. UBS also assumed that all governmental, regulatory or other consents and approvals necessary for the consummation of the merger would be obtained without any material adverse effect on Indevus, Valera or the merger. Except as described above, Indevus imposed no other instructions or limitations on UBS with respect to the investigations made or the procedures followed by UBS in rendering its opinion.

In connection with rendering its opinion to Indevus board of directors, UBS performed a variety of financial and comparative analyses that are summarized below. The following summary is not a complete description of all analyses performed and factors considered by UBS in connection with its opinion. The preparation of a financial opinion is a complex process involving subjective judgments and is not necessarily susceptible to partial analysis or summary description. With respect to the selected companies analyses and the selected transactions analysis summarized below, no company or transaction used as a comparison is either identical or directly comparable to Indevus, Valera or the merger. These analyses necessarily involve complex considerations and judgments concerning financial and operating characteristics and other factors that could affect the public trading or acquisition values of the companies concerned.

UBS believes that its analyses and the summary below must be considered as a whole and that selecting portions of its analyses and factors or focusing on information presented in tabular format, without considering all analyses and factors or the narrative description of the analyses, could create a misleading or incomplete view of the processes underlying UBS analyses and opinion. UBS did not draw, in isolation, conclusions from or with regard to any one factor or method of analysis for purposes of its opinion, but rather arrived at its ultimate opinion based on the results of all analyses undertaken by it and assessed as a whole.

The estimates of the future performance of Indevus and Valera provided by Indevus management or derived from public sources in or underlying UBS analyses are not necessarily indicative of future results or values, which may be significantly more or less favorable than those estimates. In performing its analyses, UBS considered industry performance, general business and economic conditions and other matters, many of which are beyond the control of Indevus and Valera. Estimates of the financial value of companies do not necessarily purport to be appraisals or reflect the prices at which companies actually may be sold.

The merger consideration was determined through negotiation between Indevus and Valera and the decision to enter into the merger was solely that of Indevus board of directors. UBS opinion and financial analyses were only one of many factors considered by Indevus board of directors in its evaluation of the merger and should not be viewed as determinative of the views of Indevus board of directors or management with respect to the merger or the merger consideration.

The following is a brief summary of the material financial analyses performed by UBS and reviewed with Indevus board of directors in connection with its opinion relating to the proposed merger. The financial analyses summarized below include information presented in tabular format. To fully understand UBS financial analyses, the tables must be read together with the text of each summary. The tables alone do not constitute a complete description of the financial analyses. Considering the data below without considering the full narrative description of the financial analyses, including the methodologies and assumptions underlying the analyses, could create a misleading or incomplete view of UBS financial analyses. For purposes of the analyses described below, the term implied per share value of the merger consideration refers

to the mean implied per share value of the merger consideration of \$9.76 based on the non-contingent consideration of \$7.75 plus the estimated net present value of the CSRs based on Indevus management assessments as to the timing and probability of achieving applicable milestones and utilizing discount rates ranging from 15.5% to 19.5%.

### Valera Financial Analyses

Selected Companies Analysis

UBS compared selected financial data and stock market data of Valera with corresponding data of the following seven publicly traded specialty pharmaceutical companies:

Auxilium Pharmaceuticals, Inc.

MGI Pharma, Inc.

Nabi Biopharmaceuticals

Salix Pharmaceuticals, Ltd.

Santarus, Inc.

The Medicines Company

ViroPharma Incorporated

UBS reviewed, among other things, enterprise values of the selected companies, calculated as equity market value based on closing stock prices on December 8, 2006, plus the book value of debt and minority interests, plus the liquidation value of preferred stock, less cash and cash equivalents, as a multiple of calendar years 2006, 2007 and 2008 estimated revenue. UBS then compared these multiples derived from the selected companies with corresponding revenue multiples implied for Valera based both on the closing price of Valera common stock on December 8, 2006 and the implied per share value of the merger consideration. Estimated financial data for the selected companies were based on publicly available research analysts estimates. Estimated financial data for Valera were based on internal estimates of Indevus management. This analysis indicated the following implied low, mean, median and high multiples for the selected companies, as compared to corresponding multiples implied for Valera:

	Implied Multiples				Implied Multiples			
	for Selected Companies				for Valera Based on Closing			
	Low	Mean	Median	High	Stock Price on 12/8/06	Based on Implied Per Share Value of Merger Consideration		
Enterprise Value as Multiple of:								
Revenue								
Calendar year 2006	3.0x	5.8x	5.1x	9.1x	3.2x	7.0x		
Calendar year 2007	2.4	4.2	4.3	5.7	3.0	6.4		

G 1 1 2000	2.0	2.6	0.7	<b>C</b> 1	1.7	2.6
Calendar year 2008	2.0	3.6	3.7	5.1	1./	3.6
-						

### Selected Transactions Analysis

UBS reviewed transaction values in the following 10 selected transactions involving specialty pharmaceutical companies:

Acquiror	Target
Stiefel Laboratories, Inc.	Connetics Corporation
Allergan, Inc.	Inamed Corporation
MGI Pharma, Inc.	Guilford Pharmaceuticals Inc.
Salix Pharmaceuticals, Ltd.	InKine Pharmaceutical Company, Inc.
Genzyme Corporation	Bone Care International, Inc.
Jazz Pharmaceuticals, Inc.	Orphan Medical, Inc.
Valeant Pharmaceuticals International	Xcel Pharmaceuticals, Inc.
Protein Design Labs, Inc.	ESP Pharma, Inc.
Bradley Pharmaceuticals, Inc.	Bioglan Pharmaceuticals, Inc.
Cephalon, Inc.	CIMA LABS INC.

UBS reviewed transaction values in the selected transactions as a multiple of latest 12 months revenue. UBS then compared the latest 12 months revenue multiples derived from the selected transactions with the corresponding revenue multiple implied for Valera based on the implied per share value of the merger consideration. Multiples for the selected transactions were based on publicly available information at the time of announcement of the relevant transaction. This analysis indicated the following implied low, mean, median and high multiples for the selected transactions, as compared to corresponding multiples implied for Valera:

		Implied Multiples						
		for Selected Transactions						
	Low	Mean	Median	High	Consideration			
Enterprise Value as Multiple of:								
LTM Revenue	3.4x	5.7x	5.4x	8.2x	6.7x			
Discounted Cash Flow Analysis								

UBS performed a discounted cash flow analysis to calculate the estimated present value of the unlevered, after-tax free cash flows that Valera could generate during the last nine months of fiscal year 2007 through the full fiscal year 2011 based on internal estimates of Indevus management after giving effect to the merger (inclusive of potential synergies) and potential net operating losses, or NOLs, expected by Indevus management to be utilized subject to statutory NOL carryover limitations. UBS calculated a range of terminal values by applying to Valera s fiscal year 2011 estimated earnings before interest, taxes, depreciation and amortization, or EBITDA, terminal EBITDA multiples of 8.0x to 10.0x. The cash flows and terminal values were then discounted to present value using discount rates ranging from 17.5% to 22.5%. This analysis indicated the following implied per share equity reference range for Valera, as compared to the implied per share value of the merger consideration:

#### **Implied Per Share Equity**

Reference Range for Valera \$8.54 - \$13.06

Indevus Financial Analyses

#### Selected Companies Analysis

Value of Merger Consideration \$9.76

**Implied Per Share** 

UBS compared selected financial data and stock market data of Indevus with corresponding data of the following seven publicly traded biopharmaceutical companies:

Human Genome Sciences, Inc.

Idenix Pharmaceuticals, Inc.

Nuvelo, Inc.

Telik. Inc.

Theravance, Inc.

Onyx Pharmaceuticals, Inc.

Progenics Pharmaceuticals, Inc.

UBS reviewed, among other things, enterprise values of the selected companies as a multiple of calendar years 2006, 2007 and 2008 estimated revenue. UBS then compared these multiples derived from the selected companies with corresponding revenue multiples implied for Indevus based on the closing price of Indevus common stock on December 8, 2006. Estimated financial data for the selected companies were based on publicly available research analysts estimates. Estimated financial data for Indevus were based on internal estimates of Indevus management. This analysis indicated the following implied low, mean, median and high multiples for the selected companies, as compared to corresponding multiples implied for Indevus:

#### **Implied Multiples**

		for Selected	d Companies	Implied Multiples for Indevus		
	Low	Mean	Median	High	Based on Closing Stock Price on 12/8/06	
Enterprise Value as Multiple of:				-		
Revenue						
Calendar year 2006	3.9x	6.9x	6.9x	9.9x	9.1x	
Calendar year 2007	2.2	5.6	5.6	9.0	7.2	
Calendar year 2008	1.8	5.7	5.4	9.3	6.3	

Discounted Cash Flow Analysis

UBS performed a discounted cash flow analysis to calculate the estimated present value of the standalone unlevered, after-tax free cash flows that Indevus could generate during the last nine months of fiscal year 2007 through the full fiscal year 2011 based on internal estimates of Indevus management after giving effect to potential NOLs expected by Indevus management to be utilized. UBS calculated a range of terminal values by applying terminal revenue multiples of 5.5x to 7.5x to Indevus fiscal year 2011 estimated revenue. The cash flows and terminal values were then discounted to present value using discount rates ranging from 15.5% to 19.5%. This analysis indicated the following implied per share equity reference range for Indevus, as compared to the closing price of Indevus common stock on December 8, 2006:

**Implied Per Share Equity** 

**Reference Range for Indevus** \$6.50 - \$9.82

Accretion/Dilution Analysis

UBS analyzed the potential pro forma effect of the merger on Indevus estimated earnings per share, or EPS, for fiscal years 2007 through 2011 assuming all CSRs issuable in connection with the merger would be converted into the right to receive shares of Indevus common stock. Estimated financial data for Indevus and Valera were based on internal estimates of Indevus management. Based on the total number of shares of Indevus common stock issuable in the merger and pursuant to all CSRs and the closing price of Indevus common stock on December 8, 2006, this analysis indicated that the merger could be dilutive to Indevus estimated EPS during fiscal years 2007 and 2008 and could be accretive to Indevus estimated EPS during fiscal years 2009 through 2011. Actual results may vary from projected results and the variations may be material.

**Closing Price of Indevus** 

**Common Stock on December 8, 2006** 

\$7.96

### Miscellaneous

Under the terms of UBS engagement, Indevus has agreed to pay UBS customary fees for its financial advisory services in connection with the merger, a portion of which was payable in connection with UBS

opinion and a significant portion of which is contingent upon consummation of the merger. UBS also is currently providing, and will continue to provide following the consummation of the merger, general financial advisory services to Indevus, for which UBS will receive additional compensation upon the consummation of the merger. UBS in the past acted as a financial advisor to Valera in connection with the merger and waived the fees payable by Valera to UBS for such services. In the past, UBS also provided investment banking services to Indevus and Valera unrelated to the proposed merger, for which UBS received compensation. In the ordinary course of business, UBS, its successors and affiliates may hold or trade, for their own accounts and the accounts of their customers, securities of Indevus and Valera and, accordingly, may at any time hold a long or short position in such securities.

Indevus selected UBS as its financial advisor in connection with the merger because UBS is an internationally recognized investment banking firm with substantial experience in similar transactions and is familiar with Indevus and its business. UBS is continually engaged in the valuation of businesses and their securities in connection with mergers and acquisitions, leveraged buyouts, negotiated underwritings, competitive bids, secondary distributions of listed and unlisted securities and private placements.

### **Opinion of Valera s Financial Advisor**

Valera has retained Banc of America Securities as financial advisor to Valera in connection with the proposed merger. Banc of America Securities is an internationally recognized investment banking firm which regularly engages in the valuation of businesses and their securities in connection with mergers and acquisitions, negotiated underwritings, competitive bids, secondary distributions of listed and unlisted securities, private placements and valuations for corporate and other purposes. Valera selected Banc of America Securities as financial advisor in connection with the proposed merger based on its reputation, experience and familiarity with Valera and its businesses.

On December 11, 2006, at a meeting of Valera's board of directors held to evaluate the merger, Banc of America Securities delivered to Valera's board of directors an oral opinion, which was confirmed by delivery of a written opinion dated December 11, 2006, to the effect that, as of the date of the opinion and based on and subject to various assumptions and limitations described in the opinion, the merger consideration to be received by the holders of Valera common stock (other than those holders who were entering into voting agreements in connection with the merger) was fair, from a financial point of view, to such holders.

The full text of the written opinion of Banc of America Securities to Valera's board of directors, which sets forth, among other things the procedures followed, assumptions made, matters considered and limitations on the review undertaken, is attached as *Annex C* to this joint proxy statement/prospectus, and is incorporated into this joint proxy statement/prospectus by reference. Holders of Valera common stock are encouraged to, and should, read the opinion carefully and in its entirety. The following summary of Banc of America Securities opinion is qualified in its entirety by reference to the full text of the opinion. Banc of America Securities opinion was provided to Valera's board of directors for the benefit and use of Valera's board of directors in connection with its evaluation of the merger consideration and relates only to the fairness, from a financial point of view, of the merger consideration to be received by the holders of Valera common stock (other than those stockholders of Valera who have entered into voting agreements in connection with the merger). Banc of America Securities opinion does not address any other aspect of the merger or any related transaction and does not constitute a recommendation to Valera or Indevus stockholders on how to vote or act in connection with the merger.

For purposes of its opinion, Banc of America Securities:

reviewed certain publicly available financial statements and other business and financial information of Valera and Indevus, respectively;

reviewed certain internal financial statements and other financial and operating data concerning Valera and Indevus, respectively;

reviewed certain financial forecasts relating to Indevus prepared by the management of Indevus, referred to herein as the Indevus forecasts and certain financial forecasts relating to Indevus prepared by the management of Valera, referred to herein as the Valera/Indevus forecasts, and discussed with the management of Valera its assessments as to the relative likelihood of achieving the future financial results reflected in the Indevus forecasts and the Valera/Indevus forecasts;

reviewed certain financial forecasts relating to Valera prepared by the management of Valera under alternative business scenarios reflecting varying assumptions of such management as to the future financial performance of Valera;

reviewed and discussed with the managements of Valera and Indevus certain net operating losses relating to Valera and Indevus, the benefits of which are anticipated by the respective managements of Valera and Indevus to be utilized on a standalone basis;

discussed the past and current operations, financial condition and prospects of Valera with senior executives of Valera and discussed the past and current operations, financial condition and prospects of Indevus with senior executives of Valera and Indevus;

reviewed certain information prepared by the management of Valera relating to the relative financial contributions of Valera and Indevus to the combined company;

reviewed the reported prices and trading activity for Valera common stock and Indevus common stock;

compared the financial performance of Valera and Indevus and the prices and trading activity of Valera common stock and Indevus common stock with that of certain other publicly traded companies Banc of America Securities deemed relevant;

compared certain financial terms of the merger to financial terms, to the extent publicly available, of certain other business combination transactions Banc of America Securities deemed relevant;

participated in discussions and negotiations among representatives of Valera and Indevus and their respective advisors;

reviewed the merger agreement and the forms of the contingent stock rights agreements;

considered the results of Banc of America Securities efforts to solicit, at the direction of Valera, indications of interest and proposals from third parties with respect to a possible acquisition of Valera and the fact that Valera held discussions with certain third parties with respect to a potential co-promotion arrangement with respect to certain of Valera s products as an alternative to the merger; and

performed such other analyses and considered such other factors as Banc of America Securities deemed appropriate. In arriving at its opinion, Banc of America Securities assumed and relied upon, without independent verification, the accuracy and completeness of the financial and other information it reviewed. With respect to the Indevus forecasts and the Indevus net operating losses, Banc of America Securities assumed, upon the advice of Indevus, that they have been reasonably prepared on bases reflecting the best currently available estimates and good faith judgments of the management of Indevus as to the future financial performance of Indevus and other matters covered thereby. With respect to the Valera/Indevus forecasts, the Valera forecasts and the Valera net operating losses, Banc of America Securities assumed, at the direction of Valera, that they have been reasonably prepared on bases reflecting the best currently available estimates and good faith judgments of the management of Valera as to the future financial performance of Valera, Indevus and the other matters covered thereby and, based on the assessments of the management of Valera as to the relative likelihood of achieving the future financial results reflected in the Indevus forecasts, and the Valera/Indevus forecasts, Banc of America Securities relied, at the direction of Valera, on the Valera/Indevus forecasts

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for purposes of its opinion. Banc of America Securities did not make any independent valuation or appraisal of the assets or liabilities of Valera or Indevus, nor was Banc of America Securities furnished with any such valuation or appraisals. Banc of America Securities

assumed, with the consent of Valera, that the merger will be consummated as provided in the merger agreement, with full satisfaction of all covenants and conditions set forth in the merger agreement and without any waivers thereof. Banc of America Securities also assumed, with the consent of Valera, that the merger will qualify for federal income tax purposes as a reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Banc of America Securities expressed no view or opinion as to any terms or aspects of the merger (other than the merger consideration to the extent specifically specified in its opinion) or related transactions, including, without limitation, the form or structure of the merger or the merger consideration. In addition, Banc of America Securities expressed no opinion as to the relative merits of the merger in comparison to other transactions available to Valera or in which Valera might engage or as to whether any transaction might be more favorable to Valera as an alternative to the merger, nor did Banc of America Securities express any opinion as to the underlying business decision of Valera s board of Directors of Valera to proceed with or effect the merger. Furthermore, Banc of America Securities expressed no opinion as to what the value of Indevus common stock actually would be when issued in the merger or the prices at which Indevus common stock or Valera common stock would trade at any time. Except as described above, Valera imposed no other limitations on the investigations made or procedures followed by Banc of America Securities in rendering its opinion.

Banc of America Securities opinion was necessarily based on economic, market and other conditions as in effect on, and the information made available to Banc of America Securities as of, the date of its opinion. Accordingly, although subsequent developments may affect its opinion, Banc of America Securities did not assume any obligation to update, revise or reaffirm its opinion.

The following is a summary of the material analyses contained in the presentation that was delivered to Valera s board of directors. The financial analyses summarized below include information presented in tabular format. In order to understand fully the financial analyses performed by Banc of America Securities, the tables must be read together with the accompanying text of each summary. The tables alone do not constitute a complete description of the financial analyses, including the methodologies and assumptions underlying the analyses, and if viewed in isolation could create a misleading or incomplete view of the financial analyses performed by Banc of America Securities. For purposes of the financial analyses described below, Banc of America Securities utilized financial forecasts relating to Valera prepared by Valera s management under two alternative business scenarios. The first scenario, referred to herein as the Valera Base Case, assumes that Valera will enter into a co-promotion arrangement with a third party with respect to Vantas, and the second scenario, referred to herein as the No Vantas Co-Promote Case, assumes that no co-promotion arrangement is entered into and Valera promotes Vantas without a partner. In addition, for purposes of the Valera Financial Analyses described below, Banc of America Securities calculated an implied per share value of Valera s net operating losses of \$0.48 in the case of the Valera Base Case and \$0.46 in the case of the Valera No Vantas Co-Promote Case based on the present value of the tax savings anticipated by Valera s management to result from the net operating losses and a discount rate of 14%. In the case of Indevus Financial Analyses described below, Banc of America Securities calculated an implied per share value of Indevus net operating losses of \$0.71 based on the present value of the tax savings anticipated by Indevus management to result from the net operating losses and a discount rate of 14%. For purposes of the Valera Financial Analyses, Up-Front Consideration means the non-contingent consideration of \$7.75 per share which is payable upon consummation of the merger and Implied Total Consideration means the non-contingent consideration plus the estimated present value of the CSRs based on the assessments of Valera s management as to the timing and probability of achieving applicable milestones and utilizing a discount rate of 14% which totaled \$9.81 per share.

### Valera Financial Analyses

### Analysis of Selected Public Companies

Banc of America Securities compared selected financial information for Valera with corresponding financial information for the following nine publicly traded companies in the specialty pharmaceuticals industry:

United Therapeutics Corp.	DepoMed Inc.
The Medicines Co.	MGI Pharma Inc.
Noven Pharmaceuticals Inc.	Pharmion Corp.
Auxilium Pharmaceuticals Inc.	ISTA Pharmaceuticals Inc.
Inspire Pharmaceuticals Inc.	

Banc of America Securities reviewed, among other things, enterprise values of the selected companies, calculated as fully diluted market value (based on closing stock prices on December 8, 2006) plus debt, less cash, as a multiple of calendar years 2007 and 2008 estimated revenue. Banc of America Securities also reviewed closing stock prices on December 8, 2006 of the selected companies as a multiple of calendar years 2007 and 2008 estimated earnings per share, commonly known as EPS . Banc of America Securities then applied a range of selected revenue multiples derived from the selected companies to Valera s calendar years 2007 and 2008 revenue and applied a range of selected EPS multiples derived from the selected companies to Valera s calendar years 2010 and 2011 estimated net income, which was discounted 3 and 4 years, respectively, utilizing a discount rate of 14%, in each case to derive implied per share equity reference ranges for Valera. The implied per share values for Valera s net operating losses were then added to the resulting per share equity reference ranges. Estimated financial data for the selected companies were based on publicly available research analysts estimates. Estimated financial data for Valera, as compared to the Up-Front Consideration of \$7.75 per share and the Implied Total Consideration of \$9.81 per share:

#### **Implied Per Share Equity Reference**

	Ran	ges for Val	Merger (	Merger Consideration Implied Total		
	Valera Base Case	No	Vantas Co-Promote Case	Up-Front Consideration	Consideratio	
Enterprise Value as Multiple of:						
Revenue	\$ 6.50 - \$11.50	\$	5.50 - \$9.00	\$ 7.75	\$	9.81
Equity Value as Multiple of:						
2010 Net Income	\$ 5.73 - \$ 7.75	\$	4.77 - \$ 6.42	\$ 7.75	\$	9.81
2011 Net Income	\$ 11.68 - \$15.97	\$	7.86 - \$10.72	\$ 7.75	\$	9.81

No company or business used in this analysis is identical or directly comparable to Valera or its business. Accordingly, an evaluation of the results of this analysis is not entirely mathematical. Rather, this analysis involves complex considerations and judgments concerning differences in financial and operating characteristics and other factors that could affect the public trading or other values of the companies or business segments to which Valera was compared.

#### Analysis of Selected Precedent Transactions

Banc of America Securities reviewed enterprise and equity values in the following 13 selected transactions in the specialty pharmaceuticals industry:

Acquiror	Target
Cephalon Inc.	CIMA Labs, Inc.
QLT Inc.	Atrix Laboratories Inc.
Sponsor Group	Warner Chilcott Limited
Protein Design Labs Inc.	ESP Pharma Inc.
Valeant Pharmaceuticals International	Xcel Pharmaceuticals Inc.
Jazz Pharmaceuticals, Inc.	Orphan Medical, Inc.
Genzyme Corp.	Bone Care International Inc.
Salix Pharmaceuticals, Ltd.	InKine Pharmaceutical Company, Inc.
Bayer AG	Schering AG
Merck KGaA	Serono SA
Nycomed	ALTANA Pharma AG
Stiefel Laboratories, Inc.	Connetics Corporation
Abbott Laboratories	KOS Pharmaceuticals, Inc.

Banc of America Securities reviewed enterprise values in the selected transactions as a multiple of one-year forward revenue and equity values in the selected transactions as a multiple of one-year forward EPS. Banc of America Securities then applied a range of selected revenue multiples derived from the selected transactions to Valera s calendar year 2007 revenue and a range of selected EPS multiples derived from the selected transactions to Valera s calendar year 2007 revenue and a range of selected EPS multiples derived from the selected transactions to Valera s calendar year 2010 net income which was discounted three years utilizing a discount rate of 14%, in each case to derive implied per share equity reference ranges for Valera. The implied per share values for Valera s net operating losses were then added to the resulting per share equity reference ranges. Estimated financial data for the selected transactions were based on publicly available information at the time of announcement of the applicable transaction. Estimated financial data for Valera was based on estimates of Valera s management. This analysis indicated the following implied per share equity reference ranges for Valera, as compared to the Up-Front Consideration of \$7.75 per share and the Implied Total Consideration of \$9.81 per share:

#### **Implied Per Share Equity Reference**

	Range	Ranges for Valera			Merger Consideration Implied Total		
	Valera Base Case	No Va	antas Co-Promote Case	Up-Front Consideration	Consi	ideration	
Enterprise Value as Multiple of:							
1 Year Forward Revenue	\$ 7.96 - \$10.56	\$	6.34 - \$8.27	\$ 7.75	\$	9.81	
Equity Value as Multiple of:							
One Year Forward Net Income	\$ 7.25 - \$ 9.01	\$	6.00 - \$7.44	\$ 7.75	\$	9.81	

No transaction, company or business used in this analysis is identical or directly comparable to Indevus or the merger. Accordingly, an evaluation of the results of this analysis is not entirely mathematical. Rather, this analysis involves complex considerations and judgments concerning differences in financial and operating characteristics and other factors that could affect the public trading or other values of the companies or business segments to which Indevus and the merger were compared.

#### Discounted Cash Flow Analysis

Banc of America Securities performed a discounted cash flow analysis of Valera to calculate the estimated present value as of December 31, 2006 of the stand-alone unlevered, after-tax free cash flows that Valera could generate over fiscal years 2007 through 2011 based on internal estimates of Valera's management. Banc of

America Securities calculated a range of terminal values by applying a range of earnings before income, taxes, depreciation and amortization, commonly referred to as EBITDA, multiples of 10.0x to 14.0x to Valera s fiscal year 2011 estimated EBITDA. The present value of the cash flows and terminal values were then calculated using discount rates ranging from 13% to 15%. This analysis indicated the following implied per share equity reference ranges for Valera after taking into account the implied per share value of Valera s net operating losses, as compared to the Up-Front Consideration of \$7.75 per share and the Implied Total Consideration of \$9.81 per share:

#### **Implied Per Share Equity Reference**

		Ranges for Valera		Merger C	onsideration	ı
					Im	plied
					Т	otal
				Up-Front		
	Valera Base Case	No Vant	tas Co-Promote Case	Consideration	Consid	leration
	\$8.81 - \$12.81	\$	6.24 - \$8.99	\$ 7.75	\$	9.81
T 1						

Indevus Financial Analyses

#### Analysis of Selected Public Companies

Banc of America Securities compared selected financial information for Indevus with corresponding financial data for the following nine selected publicly traded companies in the specialty pharmaceuticals industry:

United Therapeutics Corp.	Cephalon Inc.
The Medicines Co.	MGI Pharma Inc.
Medicis Pharmaceutical Corp.	Pharmion Corp.
Sepracor, Inc.	Endo Pharmaceuticals Holdings Inc.
Cubist Pharmaceuticals Inc.	_

Banc of America Securities reviewed, among other things, closing stock prices on December 8, 2006 of the selected companies as a multiple of calendar years 2007 and 2008 estimated EPS. Banc of America Securities then applied a range of selected EPS multiples derived from the selected companies to Indevus fiscal years 2012 and 2013 estimated net income which were discounted 4.75 and 5.75 years, respectively, utilizing a discount rate of 14% to derive implied per share equity reference ranges for Indevus. The implied per share value for Indevus net operating losses was then added to the resulting per share equity reference ranges. Estimated financial data for the selected companies were based on publicly available research analysts estimates. Estimated financial data for Indevus were based on internal estimates of Valera's management. This indicated the following implied per share equity reference range for Indevus, as compared to the 25-day average closing price of Indevus common stock on December 8, 2006 as well as the per share value of Indevus common stock implied by the low and high end of the collar based on the 25-day average closing price of Indevus common stock on December 8, 2006:

Furite Maleirla di	Implied Per Share Equity Reference Range for Indevus	Low End of Co Based on Closing Price of Indevus Common Stock on 12/8/	25-D: Clos Indev	ay Average sing Price of us Common Stock 1 12/8/06	Ba C Pr In Co Sta	nd of Collar sed on losing rice of devus mmon ock on 2/8/06
Equity Value as Multiple of:						
2012 Net Income	\$ 5.37 - \$7.10	\$ 6.5	5 \$	7.28	\$	8.01
2013 Net Income	\$ 5.90 - \$7.81	\$ 6.5	5 \$	7.28	\$	8.01

No company or business used in this analysis is identical or directly comparable to Valera or its business. Accordingly, an evaluation of the results of this analysis is not entirely mathematical. Rather, this analysis involves complex considerations and judgments concerning differences in financial and operating characteristics and other factors that could affect the public trading or other values of the companies or business

segments to which Valera was compared.

#### Discounted Cash Flow Analysis

Banc of America Securities performed a discounted cash flow analysis of Indevus to calculate the estimated present value as of December 31, 2006 of the stand-alone unlevered, after-tax free cash flows that Indevus could generate over fiscal years 2007 through 2013 based on internal estimates for Indevus prepared by Valera s management. Banc of America Securities calculated a range of terminal values by applying a range of EBITDA multiples of 10.0x to 14.0x to Indevus fiscal year 2013 estimated EBITDA. The present value of the cash flows and terminal values were then calculated using discount rates ranging from 13% to 15%. This analysis indicated the following implied per share equity reference ranges for Indevus after taking into account the implied per share value of Indevus net operating losses, as compared to the 25-day average closing price of Indevus common stock on December 8, 2006 as well as the per share value of Indevus common stock implied by the low and high end of the collar based on the 25-day average closing price of Indevus common stock on December 8, 2006:

	Implied Per Share Equity Reference	Based on the	of Collar he Average Price of	Closin	y Average g Price of s Common	Based on	d of Collar the Average g Price of
	Range for Indevus	Indevus Cor	nmon Stock	Stock Pri	or to 12/8/06	Indevus Co	ommon Stock
	\$4.76 - \$6.90	\$	6.55	\$	7.28	\$	8.01
0.1							

#### **Other Factors**

In rendering its opinion, Banc of America Securities also reviewed and considered other factors, including:

the implied exchange ratios based on average of the closing prices of Valera common stock and Indevus common stock for one-week, one-month, two-month, three-month and six-month period prior to December 8, 2006;

the implied exchange ratios based on the implied per share equity reference ranges derived for Valera and Indevus in the financial analyses described above;

relative contributions of Valera and Indevus to the combined company s estimated net income, revenue and EBITDA for the fiscal year 2011 based on internal forecasts for Valera and Indevus prepared by Valera s management; and

historical trading prices and trading volumes of Valera common stock since the initial public offering of Valera common stock on February 2, 2006 and historical trading prices and trading volumes of Indevus common stock during the 12-month period ended December 8, 2006.

#### Miscellaneous

As noted above, the discussion set forth above is a summary of the material financial analyses presented by Banc of America Securities to Valera s board of directors in connection with its opinion and is not a comprehensive description of all analyses undertaken by Banc of America Securities in connection with its opinion. The preparation of a financial opinion is a complex analytical process involving various determinations as to the most appropriate and relevant methods of financial analysis and the application of those methods to the particular circumstances and, therefore, a financial opinion is not readily susceptible to partial analysis or summary description. Banc of America Securities believes that its analyses summarized above must be considered as a whole. Banc of America Securities further believes that selecting portions of its analyses and the factors considered or focusing on information presented in tabular format, without considering all analyses and factors or the narrative description of the analyses, could create a misleading or incomplete view of the processes underlying Banc of America Securities analyses and opinion. Banc of America Securities did not assign any specific weight to any of the analyses described above. The fact that any specific analysis has been referred to in the summary above is not meant to indicate that such analysis was given greater weight than any other analysis referred to in the summary.

In performing its analyses, Banc of America Securities considered industry performance, general business and economic conditions and other matters, many of which are beyond Valera's control. The estimates of the future performance of Valera and Indevus provided by Valera's and Indevus' respective managements in or underlying Banc of America Securities' analyses are not necessarily indicative of actual values or actual future results, which may be significantly more or less favorable than those estimates or those suggested by Banc of America Securities' analyses. These analyses were prepared solely as part of Banc of America Securities' analysis of the fairness of the merger consideration from a financial point of view, and were provided to Valera's board of directors in connection with the delivery of Banc of America Securities' opinion. The analyses do not purport to be appraisals or to reflect the prices at which a company might actually be sold or the prices at which any securities have traded or may trade at any time in the future. Accordingly, the estimates used in, and the ranges of valuations resulting from, any particular analysis described above are inherently subject to substantial uncertainty and should not be taken to be Banc of America Securities view of the actual value of Valera.

The type and amount of consideration payable in the merger were determined through negotiations between Valera and Indevus, rather than by any financial advisor, and were approved by Valera's board of directors. The decision to enter into the merger agreement was solely that of Valera's board of directors. As described above, Banc of America Securities opinion and the financial analyses described above were only one of a number of factors considered by Valera's board of directors in its evaluation of the merger and should not be viewed as determinative of the views of Valera's board of directors or its management with respect to the merger or the type and amount of consideration payable in the merger.

Pursuant to the engagement letter between Banc of America Securities and Valera, Valera has agreed to pay Banc of America Securities for its services in connection with the merger an aggregate fee of approximately \$1,500,000, a portion of which was payable in connection with the rendering of Banc of America Securities opinion and the remaining portion of which is payable upon consummation of the merger. Valera also has agreed to reimburse Banc of America Securities for its reasonable expenses, including reasonable fees and disbursements of Banc of America Securities legal counsel, and to indemnify Banc of America Securities, any controlling person of Banc of America Securities and each of their respective directors, officers, employees, agents, affiliates and representatives against specified liabilities, including liabilities under the federal securities laws.

Banc of America Securities or its affiliates have provided and may in the future provide financial advisory and financing services to Valera and Indevus and have received or may in the future receive fees for the rendering of these services, including having acted as joint book-running manager to Valera in connection with its initial public offering. In the ordinary course of its businesses, Banc of America Securities and its affiliates may actively trade the debt and equity securities or loans of Valera and Indevus for its own account or for the accounts of customers, and accordingly, Banc of America Securities or its affiliates may at any time hold long or short positions in such securities or loans.

# Additional Interests of Valera Directors and Executive Officers in the Merger

In considering the recommendation of Valera s board of directors, Valera stockholders should be aware of the interests that certain Valera executive officers and directors may have in the merger that may be different from, or in addition to, their interests as Valera stockholders generally. These interests include:

severance and other payments and benefits to certain executive officers of Valera pursuant to existing change in control and employment agreements with Valera and a consulting arrangement between Dr. David S. Tierney, Valera s President and Chief Executive Officer, and Indevus during a transition period after the completion of the merger;

share issuances to Valera executive officers and directors in consideration of the cancellation of all options to purchase Valera common stock in connection with the merger;

employment agreements expected to be entered into between Indevus and certain officers of Valera, and, in the case of James C. Gale, Valera s chairman of the board, an expected membership on Indevus board of directors;

rights to continued director and executive officer indemnification and insurance coverage by Indevus after the merger for acts or omissions that occurred before the merger;

registration rights covering the shares of Indevus common stock acquired by SMH (and affiliated entities; James C. Gale, Valera s chairman of the board, is the chief investment officer of these SMH affiliated entities) in connection with the merger for resale under the Securities Act on a Registration Statement on Form S-3 to be filed by Indevus within 30 days following the effective time of the merger; and

severance payments to another officer of Valera pursuant to the Severance Pay Plan established by Indevus in connection with the merger.

As a result, the directors and executive officers of Valera may be more likely to recommend approval of the merger proposal than if they did not have these interests. The Valera board of directors was aware of these interests and considered them, among other matters, in reaching its decisions to declare the merger and the other transactions contemplated by the merger agreement advisable, to adopt the merger agreement and to recommend that Valera s stockholders vote in favor of adopting the merger agreement.

#### Severance Payments under Existing Agreements and the Consulting Arrangement

#### Agreements with David S. Tierney, M.D.

Valera entered into an Amended and Restated Executive Employment Agreement (the Employee Agreement ), as amended, with David S. Tierney, M.D., Valera's President and Chief Executive Officer for which severance payments will be made as a result of the merger. Under the Employee Agreement, if, among other reasons, a change in control occurs, Dr. Tierney will continue to receive his then current base salary for the 24-month period following the date of the change in control and will receive a bonus equal to two times the highest annual bonus received by him during the three most recently completed fiscal years of Valera. The estimated payment to be made to Dr. Tierney in connection with the change in control provisions of the Employment Agreement as a result of the merger is expected to be \$935,000. This estimated amount includes base salary and bonus but does not reflect regular bonus payments earned but not paid and accrued vacation earned but not taken. Under the Employee Agreement, all payments to Dr. Tierney in connection with a change in control are subject to reduction to the extent that the reduction would avoid the imposition of certain golden parachute excise taxes and thereby increase Dr. Tierney is net after-tax proceeds.

Under the Employee Agreement, Dr. Tierney will be paid an annual base salary of \$350,000 and will be eligible to participate in any annual bonus program established by Valera s board of directors and benefit plans and programs that are generally available to other employees of Valera. Valera s board of directors (excluding Dr. Tierney if he is a director) will review the performance of Dr. Tierney annually and make appropriate adjustments to Dr. Tierney s base salary.

In addition, Indevus has entered into a short-term consulting arrangement with Dr. David S. Tierney pursuant to which Dr. Tierney will consult on European approvals and general corporate matters for the one-month period following the closing of the merger in exchange for a consulting fee equal to one month of Dr. Tierney s annual base salary for Valera, as then in effect at the time of the closing, with reimbursement for approved expenses.

#### Change in Control Agreements with other Executive Officers

Valera has entered into change in control agreements, as amended, with the following executive officers for which severance payments will be made as a result of the merger: Andrew Drechsler, Jeremy Middleton, and Matthew Rue. The estimated severance payments that would be made to each of the executives in connection with a qualifying termination of employment pursuant to their change in control agreements as a result of the merger are as follows:

	Estimated
Name	Amount
Andrew Drechsler	\$ 640,000
Jeremy Middleton	\$ 275,000
Matthew Rue	\$ 265,000

These estimated amounts include base salary, bonus and health benefits if applicable but do not reflect regular bonus payments earned but not paid and accrued vacation earned but not taken.

Under the agreements, if, among other reasons, a change in control (as defined in the agreements to include the merger) occurs, then the executive will be entitled to a severance payment equal to the sum of his or her annual base salary and bonus amount, except that in the case of Mr. Drechsler, the severance payment will be equal to the product of two times the sum of his then current base salary and the bonus amount.

Bonus amount is defined in the agreements as the executive s target annual bonus or, after the first anniversary of the date the agreement was entered into, the highest annual bonus received by the executive during the past three years (or such lesser number of years the executive was employed by Valera). The agreements also provide for payment of any unpaid bonus earned with respect to the year ended prior to the date the executive s employment terminated and the waiver of any applicable COBRA premiums for the executive (and, if applicable, his or her spouse and dependents) for a period commensurate with the period covered by the severance payment. Under the agreements, all payments to an executive in connection with a change in control are subject to reduction to the extent that the reduction would avoid the imposition of certain

golden parachute excise taxes and thereby increase the executive s net after-tax proceeds. Payment of benefits is conditioned upon execution by the executive of a release and the executives are subject to confidentiality and proprietary information covenants following cessation of employment.

Valera has similar agreements with Petr F. Kuzma and Kevin Pelin except that neither executive is expected to receive severance payments as a result of the merger because each is expected to be employed by Indevus following the merger. See Employment Agreements with Indevus .

#### Equity Compensation Awards

The merger agreement provides that upon completion of the merger, each compensatory Valera stock option, including those held by Valera s executive officers and directors, will be cancelled in consideration of receipt of Indevus common stock (and cash in lieu of fractional shares) and/or, upon election, Indevus unfunded and unsecured promise to issue, in the future, the number of shares of Indevus common stock that would have been issuable had option holders received CSRs.

The following table shows the number of shares of Indevus common stock to be received relating to such cancelled options in connection with the merger, including all potential future issuances of Indevus common stock pursuant to the merger agreement, and the value of such shares of Indevus common stock, based on Valera equity compensation awards held by Valera s executive officers and directors as of March 1, 2007. In determining the amounts shown on this table, Valera has used the unaudited pro forma condensed consolidated financial statements contained in this joint proxy statement/prospectus, including an assumed exchange ratio for the merger of 1.1687, an assumed volume weighted average trading price of Indevus common stock used to derive the exchange ratio of \$6.63, which incorporates the average trading price of Indevus common stock for the 25 trading days ending five trading days prior to March 1, 2007 (a date selected by Indevus management to estimate the preliminary purchase price for the purpose of filing the registration statement of which this joint proxy statement/prospectus is a part), and an assumed fair value of \$6.76 for the Indevus common stock based on the closing price of the common stock on March 1, 2007.

Name	Number of Options to be Cancelled	Number of Shares to be Received	Value of Shares t be Received	
Executive Officers:				
David S. Tierney, M.D.	502,500	589,083	\$	3,982,201
Andrew T. Drechsler	109,166	10,180	\$	68,817
Petr F. Kuzma	93,334	107,089	\$	723,922
Jeremy D. Middleton	40,000	14,479	\$	97,878
Matthew L. Rue, III	136,666	151,959	\$	1,027,243
Directors:				
James C. Gale (1)	20,833	19,304	\$	130,495
David R. Dantzker, M.D.	22,500	21,379	\$	144,522
Jerome Feldman	15,000	12,046	\$	81,431
Hubert Huckel, M.D.	11,458	7,639	\$	51,640
Jeffrey M. Krauss (2)	22,500	21,379	\$	144,522
Ogden R. Reid	22,500	21,379	\$	144,522
Howard Silverman	22,500	21,379	\$	144,522
John T. Spitznagel	36,666	39,006	\$	263,681

(1) Includes options held by SMH Hydro Med, LLC, SMH Hydro Med II, LLC, SMH Valera, LLC, Corporate Opportunities Fund, L.P., by Corporate Opportunities Fund (Institutional), L.P., Life Sciences Opportunities Fund, L.P., Life Sciences Opportunities Fund (Institutional), L.P., each an affiliate of Sanders Morris Harris, Inc. Mr. Gale has sole voting and dispositive power over the options held by Sanders Morris Harris Inc.

(2) Represents options held by Psilos Group. Mr. Krauss is a managing director of Psilos Group.

# **Employment Agreements with Indevus**

*Employment Agreement with Petr Kuzma*. Indevus and Petr Kuzma have executed an offer letter relating to a position as Indevus Senior Vice President, Research & Development, subject to the successful completion of the merger. This conditional offer covers a two-year term of employment with Indevus, commencing at the time the merger closes and at the expiration of such term, Indevus would provide Mr. Kuzma with a one-year consulting arrangement. The estimated base salary to be paid to Mr. Kuzma is expected to be \$230,000 per year and Mr. Kuzma would also be eligible to an annual bonus of up to 30% percent of his base salary if specified corporate and personal performance goals are met for each year. Mr. Kuzma would receive a retention bonus, equal to one twelfth of his base salary, which would be payable three months following the closing date of the merger provided that Mr. Kuzma remains an employee in good standing and in continuous service with Indevus through such payment date. In addition, subject to approval of the Indevus board of directors, pursuant to the terms of the offer Mr. Kuzma would be granted an option to purchase 150,000 shares of Indevus common stock with an exercise price equal to the closing price of the common stock on the date of grant. Such stock option will vest and become exercisable with respect to 25% of the shares after the end of one year of employment, and

6.25% of the shares will vest and become exercisable on the last day of each of the next 12 calendar quarters thereafter provided Mr. Kuzma remains an Indevus employee.

*Employment Agreement with Kevin Pelin*. Indevus and Kevin Pelin, an executive officer of Valera, have executed an offer letter relating to a position as Indevus Senior Vice President, Operations and General Manager, subject to the successful completion of the merger. The estimated base salary to be paid to Mr. Pelin is expected to be \$230,000 per year and Mr. Pelin would also be eligible to an annual bonus of up to 30% percent of his base salary if specified corporate and personal performance goals are met for each year. Mr. Pelin would receive a retention bonus, equal to one twelfth of his base salary, which would be payable three months following the closing date of the merger provided that Mr. Pelin remains an employee in good standing and in continuous service with Indevus through such payment date. In addition, subject to approval of the Indevus board of directors, pursuant to the terms of the offer Mr. Pelin would be granted an option to purchase 150,000 shares of Indevus common stock with an exercise price equal to the closing price of the common stock on the date of grant. Such stock option will vest and become exercisable with respect to 25% of the shares after the end of one year of employment, and 6.25% of the shares will vest and become exercisable on the last day of each of the next 12 calendar quarters thereafter provided Mr. Pelin remains an Indevus employee.

#### Indemnification and Directors and Officers Insurance

Valera s directors and officers will have the right under the merger agreement to continued indemnification and insurance coverage for acts and omissions occurring prior to the merger. See The Merger Agreement Covenants and Agreements *Indemnification* below.

# **Registration Rights**

Indevus has agreed to provide registration rights covering the shares of Indevus common stock acquired by SMH (and affiliated entities; James C. Gale, Valera s chairman of the board, is the chief investment officer of those SMH affiliated entities) in connection with the merger for resale under the Securities Act on a Registration Statement on Form S-3 to be filed by Indevus within 30 days following the effective time of the merger.

#### Severance Pay Plan

In connection with the execution of the merger agreement, Indevus also adopted a Severance Pay Plan for certain Valera employees, including Richard Caulfield, an executive officer of Valera. The value of Mr. Caulfield s severance and benefits under the Severance Plan is \$107,949. The purpose of the Severance Pay Plan is to provide payments on a discretionary basis to employees of Valera whose employment is terminated as the result of a change of control of Valera, such as the merger. In essence, benefits under the Severance Pay Plan are intended to be supplemental unemployment benefits.

All regular, active, full-time employees of Valera are eligible participants under the Severance Pay Plan, other than:

any employee party to any written agreement or offer letter providing cash severance benefits for any termination of employment otherwise covered by the Severance Pay Plan;

temporary employees;

any individual characterized by Valera as an independent contractor; and

any other individual who is not treated by Valera as an employee for purposes of withholding federal income taxes. To receive a severance payment under the Severance Pay Plan, an eligible participant must:

be terminated in connection with a change of control of Valera, such as the merger; and

sign and not revoke a release discharging Valera and all affiliated persons and entities from any claims, demands and causes of action (other than claims relating to vested benefits under Valera benefit plans).

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Eligible participants will not receive severance payments under the Severance Pay Plan if:

they voluntarily resign from Valera, including in connection with retirement;

they are terminated in connection with a change of control of Valera, but are offered a comparable job with Valera or any successor and refuse the job;

they are terminated in connection with a change of control of Valera, and are offered and accept a non-comparable job with Valera or any successor;

they are discharged involuntarily for job performance problems, violations of Valera rules, or for cause, as defined in the Severance Pay Plan, or if after they are terminated, Valera discovers that they had engaged in conduct that constitutes cause during or after their employment with Valera;

they are covered by a collective bargaining agreement; or

they leave under circumstances other than those specified above for eligible participants.

Determination of the severance benefit payable to any eligible employee under the Severance Pay Plan is based upon years of service and such other factors determined to be relevant by Valera in its sole discretion. In the absence of any other determination, the amount of severance pay will be determined as follows:

if the eligible employee s official title is below manager, they will receive severance pay equal to twelve weeks of their weekly base pay;

if the eligible employee s official title is manager or above, they will receive sixteen weeks of their weekly base pay; and

notwithstanding the eligible employee s title, if they have completed five or more years of service with Valera, they will receive severance pay equal to four weeks of their weekly base pay in addition to the severance pay to which they are entitled under the first two bullets above.

#### **Directors and Management of Indevus Following the Merger**

#### **Board of Directors**

James C. Gale, chairman of the board of directors of Valera and chief investment officer of the Corporate Opportunities Funds and Life Sciences Opportunities Fund, affiliates of Sanders Morris Harris, has been nominated for election to Indevus board of directors at Indevus annual and special meeting. Otherwise, the composition of the board of directors of Indevus will continue unchanged by the merger. Information regarding nominees for election to Indevus board of directors can be found in the section entitled Proposal #2 Election of Directors beginning on page 224.

#### **Executive** Officers

Indevus executive officers will not change as a result of the transaction. Information about Indevus executive officers, including biographical information, executive compensation and relationships and related transactions between Indevus and its management, can be found in the section

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entitled Proposal #2 Election of Directors beginning on page 224.

# Material United States Federal Income Tax Consequences

The following is a discussion of the material U.S. federal income tax consequences of the merger to Valera stockholders who exchange their shares of Valera common stock for shares of Indevus common stock and CSRs in the merger. This discussion addresses only Valera stockholders who are U.S. Holders (as defined below) and hold Valera common stock as a capital asset. It does not address all of the U.S. federal income tax consequences

that may be relevant to a particular Valera stockholder in light of that stockholder s individual circumstances or to a Valera stockholder who is subject to special rules, including, without limitation:

a financial institution or insurance company;

a tax-exempt organization;

a stockholder who is not a U.S. Holder;

a pass-through entity or an investor in such an entity;

a dealer or broker in securities or foreign currencies;

a trader in securities who elects to apply a mark-to-market method of accounting;

a stockholder who holds Valera common stock as part of a hedge, appreciated financial position, straddle, constructive sale or conversion transaction;

a stockholder who exercises dissenters rights; and

a stockholder who acquired his or her shares of Valera common stock pursuant to the exercise of employee stock options or otherwise as compensation.

The following discussion is based on the Code, applicable Treasury regulations, administrative interpretations and court decisions, each as in effect as of the date of this document and all of which are subject to change, possibly with retroactive effect. This discussion is not binding on the Internal Revenue Service, or IRS, and there can be no assurance that the IRS or a court will agree with the conclusions stated herein. In addition, this discussion does not address any state, local or foreign tax consequences of the merger.

# Valera stockholders are urged to consult their tax advisors as to the specific tax consequences to them of the merger in light of their particular circumstances including the applicability and effect of U.S. federal, state, local, foreign income and other tax laws.

For purposes of this discussion, U.S. Holder refers to a beneficial holder of Valera common stock that is, for U.S. federal income tax purposes, (i) an individual citizen or resident of the United States, (ii) a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income taxation regardless of its source or (iv) a trust (x) that is subject to the supervision of a court within the United States and the control of one or more U.S. persons or (y) that was in existence on August 20, 1996 and has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

If an entity treated as a partnership for U.S. federal income tax purposes holds Valera common stock, the tax treatment of a partner will generally depend upon the status of the partner and the activities of that partnership. If a U.S. Holder is a partner of a partnership holding that common stock, the holder should consult its tax advisor regarding the tax consequences of the merger.

It is a condition to the completion of the merger that Indevus receive a written opinion from its counsel, Skadden, Arps, Slate, Meagher & Flom LLP, and that Valera receive a written opinion from its counsel, Pepper Hamilton LLP, in each case dated as of the effective date of the merger,

to the effect that the merger will qualify as a reorganization within the meaning of Section 368(a) of the Code. Neither Indevus nor Valera intends to waive this closing condition. In the event that either Indevus or Valera waives receipt of such opinion from its counsel, however, the waiving company will again solicit the approval of its stockholders after providing appropriate disclosure. The opinions will rely on certain assumptions as well as representations made by Indevus, Hayden Merger Sub, Inc. and Valera. If any of those assumptions or representations are inaccurate, counsel may not be able to render the required opinions, or the opinions could become invalid as a result, and the tax consequences of the merger could differ from those discussed here. An opinion of counsel is not binding on the

IRS or any court, nor does it preclude the IRS from adopting a contrary position. No ruling has been or will be sought from the IRS on the U.S. federal income tax consequences of the merger.

# TAX CONSEQUENCES TO VALERA STOCKHOLDERS

Assuming that the merger qualifies as a reorganization within the meaning of Section 368(a) of the Code, the following are the material U.S. federal income tax consequences of the merger to Valera stockholders:

#### Exchange of Valera Common Stock for Indevus Common Stock and CSRs

Except as discussed below with respect to the receipt of cash in lieu of fractional shares and any portion of additional shares of Indevus common stock received pursuant to the CSRs that is treated as imputed interest, Valera s stockholders will not recognize gain or loss for U.S. federal income tax purposes on their receipt of Indevus common stock or the CSRs in exchange for their Valera common stock in the merger.

# Basis and Holding Period of Merger Consideration

The aggregate tax basis of the Indevus common stock and the CSRs received by a Valera stockholder pursuant to the merger will be the same as the aggregate tax basis of the Valera stockholder s surrendered common stock exchanged therefor, reduced by the tax basis allocable to any fractional share of Indevus common stock received. The tax basis will be allocated among the CSRs and the Indevus common stock as though the Valera stockholder received the maximum number of shares that can be issued under the CSRs.

An adjustment to the basis in the Indevus common stock received and the CSRs should be made once it becomes known how many shares (if any) the holders of the CSRs are entitled to receive. It is unclear how this adjustment should be made, particularly if a Valera stockholder no longer retains all the Indevus common stock or CSRs received in the merger. The IRS has not issued guidelines on how a stockholder should make this adjustment. A Valera stockholder could recalculate its basis in any remaining Indevus common stock or additional Indevus common stock received from the CSRs without recalculating the basis that had been allocated to any disposed merger consideration. Alternatively, a Valera stockholder could recalculate its basis in all of its Indevus common stock, including additional Indevus common stock received from the CSRs, and CSRs, even if the stockholder has disposed of some of its Indevus common stock. Each Valera stockholder should consult its own tax advisor as to the allocation of its tax basis among the Indevus common stock and the CSRs.

The holding period of the Indevus common stock and the CSRs in the hands of a Valera stockholder will include the holding period of the Valera stockholder s common stock exchanged for the Indevus common stock and the CSRs pursuant to the merger.

#### Cash in Lieu of Fractional Shares

A Valera stockholder who receives cash instead of a fractional share of Indevus common stock in the merger will be treated as having received the fractional share in the merger and then as having received the cash in exchange for the fractional share and should generally recognize capital gain or loss equal to the difference between the amount of the cash received instead of a fractional share and the stockholder s tax basis allocable to such fractional share. Any such capital gain or loss will be a long-term capital gain or loss if the Valera common stock exchanged for the fractional share of Indevus common stock was held for more than one year at the time of the merger.

# Conversion of the CSRs

Upon the conversion of CSRs for shares of Indevus common stock:

no gain or loss would be recognized, except with respect to cash received in lieu of a fractional share and, as described below, any portion of the Indevus shares received pursuant to the CSRs that is treated as imputed interest will be taxed as ordinary interest income;

the tax basis in the Indevus common stock received on conversion will be determined initially as set forth above under the section titled Basis and Holding Period of Merger Consideration, and will be reduced by any basis allocable to any fractional share and increased by the portion of such stock treated as imputed interest; and

the holding period of the Indevus common stock received will include the holding period of the CSR, except that the portion of the additional shares of Indevus common stock received pursuant to the CSRs which represents the receipt of imputed interest, as described below, will begin a new holding period upon receipt of such additional shares.

When you sell or otherwise dispose of your shares of Indevus common stock received in the merger or upon conversion of the CSRs, you will generally recognize capital gain or loss in an amount equal to the difference between the amount you realize for the shares and your tax basis in the shares. Individuals are generally entitled to a reduced rate of tax on capital gains with respect to property held for more than one year.

#### Imputed Interest on Additional Shares Received Pursuant to the CSRs

the recipient and to the IRS the amount of such interest income as required by the Code.

Under current law the deferred receipt of additional shares in a reorganization, such as those to be received pursuant to the CSRs, requires that a portion of the additional shares be treated as interest income. Where there is no express provision for interest, as is the case here, under the current regulations interest may be imputed under Section 483 of the Code. Thus, if additional shares become payable more than one year after the merger, a portion of any shares payable more than six months after the date of the merger will constitute ordinary interest income. The amount of such interest income will be calculated by taking the fair market value of any additional shares issued and discounting such amount from the date of issuance back to the time of the merger using the imputed interest rate under the Code. The imputed interest rate will be the applicable federal rate provided under Section 1274(d) of the Code as of the time of the merger. Thus, the longer the period of time until the additional shares are received, the greater the proportion of such shares that will be treated as ordinary interest income. Each additional share received will be deemed to represent its pro rata share of the interest income. Upon the issuance of any additional shares, Indevus will report to

# Reporting Requirements

A Valera stockholder will be required to retain records pertaining to the merger and may be required to file with such Valera stockholder s U.S. federal income tax return for the year in which the merger takes place a statement setting forth certain facts relating to the merger.

THE DISCUSSION OF MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES SET FORTH ABOVE IS NOT INTENDED TO BE A COMPLETE ANALYSIS OR DESCRIPTION OF ALL POTENTIAL UNITED STATES FEDERAL INCOME TAX CONSEQUENCES OF THE MERGER. MOREOVER, THE DISCUSSION SET FORTH ABOVE DOES NOT ADDRESS TAX CONSEQUENCES THAT MAY VARY WITH, OR ARE CONTINGENT UPON, INDIVIDUAL CIRCUMSTANCES. IN ADDITION, THE DISCUSSION SET FORTH ABOVE DOES NOT ADDRESS ANY NON-INCOME TAX OR ANY FOREIGN, STATE OR LOCAL TAX CONSEQUENCES OF THE MERGER AND DOES NOT ADDRESS THE TAX CONSEQUENCES OF ANY TRANSACTION OTHER THAN THE MERGER.

# Accounting Treatment of the Merger

The merger will be accounted for as an acquisition of Valera by Indevus under the purchase method of accounting under U.S. GAAP. Under the purchase method of accounting, the assets and liabilities of the acquired company are, as of completion of the merger, recorded at their respective fair values and added to those of the reporting public issuer, including an amount for goodwill representing the difference between the purchase price

and the fair value of the identifiable net assets. Financial statements of Indevus issued after consummation of the merger will reflect only the operations of Valera after the merger and will not be restated retroactively to reflect the historical financial position or results of operations of Valera.

All unaudited pro forma financial information contained in this document has been prepared using the purchase method to account for the merger. The final allocation of the purchase price will be determined after the merger is completed and after completion of an analysis to determine the assigned fair values of Valera s tangible and identifiable intangible assets and liabilities. In addition, estimates related to restructuring and merger-related charges are subject to final decisions related to combining Valera into Indevus. Accordingly, the final purchase accounting adjustments may be materially different from the unaudited pro forma adjustments. Any decrease in the net fair value of the assets and liabilities of Valera as compared to the unaudited pro forma information included in this document will have the effect of increasing the amount of the purchase price allocable to goodwill.

# **Regulatory Matters Related to the Merger**

Indevus and Valera are not aware of any material governmental or regulatory requirements that must be complied with regarding the merger, other than the effectiveness of the registration statement of which this joint proxy statement/prospectus is a part and compliance with applicable provisions of Delaware law.

#### Merger Fees, Costs and Expenses

Indevus and Valera will each bear one-half of the expenses incurred in connection with the filing, printing and mailing of this joint proxy statement/prospectus and otherwise, generally, will bear their own expenses related to the merger. However, under certain circumstances, one party may be required to reimburse up to \$3.0 million of the expenses of the other party, and, under other circumstances, one party may be required to pay the other party a termination fee. See the section entitled The Merger Agreement Covenants and Agreements *Fees and Expenses* below.

#### **Appraisal Rights for Valera Stockholders**

Under Delaware law, Valera stockholders have the right to dissent from the merger and to receive payment in cash for the fair value of their shares of Valera common stock, as determined by the Delaware Chancery Court. Valera stockholders electing to exercise appraisal rights must comply with the provisions of Section 262 of the Delaware General Corporation Law in order to perfect their rights. Valera will require strict compliance with these statutory procedures. A copy of Section 262 is included as *Annex H* to this joint proxy statement/prospectus.

The following is a brief summary of the material provisions of the Delaware statutory procedures required to be followed by a stockholder in order to dissent from the merger and perfect the stockholder s appraisal rights. This summary, however, is not a complete statement of all applicable requirements and is qualified in its entirety by reference to Section 262 of the Delaware General Corporation Law. If a Valera stockholder wishes to consider exercising its appraisal rights, the Valera stockholder should carefully review the full text of Section 262 contained in *Annex H* because failure to timely and properly comply with the requirements of Section 262 will result in the loss of appraisal rights under Delaware law.

Section 262 requires that stockholders of record on the record date be notified not less than 20 days before the special meeting to vote on the merger for which dissenters appraisal rights will be available. A copy of Section 262 must be included with such notice. This joint proxy statement/prospectus constitutes Valera s notice to its stockholders of the availability of appraisal rights in connection with the merger in compliance with the requirements of Section 262.

If a Valera stockholder elects to demand appraisal of its shares, the following conditions must be satisfied:

1. The stockholder must deliver to Valera a written demand for appraisal of its shares before the vote is taken on the merger agreement at the special meeting. This written demand for appraisal must be in addition to and separate from any proxy or vote abstaining from or voting against the merger. Voting against or failing to vote for the merger itself does not constitute a demand for appraisal under Section 262.

2. The stockholder must not vote in favor of the merger. A vote in favor of the merger, by proxy or in person, will constitute a waiver of the stockholder s appraisal rights in respect of the shares so voted and will nullify any previously filed written demands for appraisal.

If a Valera stockholder fails to comply with either of these conditions, and the merger is completed, the stockholder will be entitled to receive the shares of Indevus common stock, CSRs and cash in lieu of fractional shares for its shares of Valera common stock as provided for in the merger agreement, but will have no appraisal rights with respect to its shares of Valera common stock.

All demands for appraisal should be addressed to Valera Pharmaceuticals, Inc., 7 Clarke Drive, Cranbury, NJ 08512, Attention: Corporate Secretary, should be delivered before the vote on the merger is taken at the special meeting and should be executed by, or on behalf of, the record holder of the shares of Valera common stock. The demand must reasonably inform Valera of the identity of the stockholder and the intention of the stockholder to demand appraisal of his, her or its shares.

To be effective, a demand for appraisal by a holder of Valera common stock must be made by, or in the name of, such record stockholder, fully and correctly, as the stockholder s name appears on his or her stock certificate(s) and cannot be made by the beneficial owner if he or she does not also hold the shares of record. The beneficial holder must, in such cases, have the record owner submit the required demand in respect of such shares.

If shares are owned of record in a fiduciary capacity, such as by a trustee, guardian or custodian, execution of a demand for appraisal should be made in such capacity; and if the shares are owned of record by more than one person, as in a joint tenancy or tenancy in common, the demand should be executed by or for all joint owners. An authorized agent, including an authorized agent for two or more joint owners, may execute the demand for appraisal for one or more stockholders of record; however, the agent must identify the record owner or owners and expressly disclose the fact that, in executing the demand, he or she is acting as agent for the record owner or owners. A record owner, such as a broker, who holds shares as a nominee for others, may exercise his, her or its right of appraisal with respect to the shares held for one or more beneficial owners. In such case, the written demand should state the number of shares as to which appraisal is sought. Where no number of shares is expressly mentioned, the demand will be presumed to cover all shares held in the name of such record owner.

If a Valera stockholder holds its shares of Valera common stock in a brokerage or bank account or in other nominee form and the stockholder wishes to exercise appraisal rights, the stockholder should consult with its broker or bank or such other nominee to determine the appropriate procedures for the making of a demand for appraisal by such nominee.

Within 10 days after the effective date of the merger, the surviving entity must give written notice of the date the merger became effective to each Valera stockholder who has properly filed a written demand for appraisal and who did not vote in favor of the merger. Within 120 days after the effective date of the merger, either the surviving entity or any stockholder who has complied with the requirements of Section 262 may file a petition in the Delaware Chancery Court demanding a determination of the fair value of the shares held by all stockholders entitled to appraisal. The surviving entity has no obligation to file such a petition in the event there are dissenting stockholders. Accordingly, the failure of a stockholder to file such a petition within the period specified could nullify such stockholder s previous written demand for appraisal.

At any time within 60 days after the effective date of the merger, any stockholder who has demanded an appraisal has the right to withdraw the demand and to accept the shares of Indevus common stock and contingent stock rights specified by the merger agreement for his or her shares of Valera common stock. Any attempt to withdraw an appraisal demand more than 60 days after the effective date of the merger will require the written approval of the surviving entity. Within 120 days after the effective date of the merger, any stockholder who has complied with Section 262 will be entitled, upon written request, to receive a statement setting forth the aggregate number of shares of Valera common stock not voted in favor of the merger and with respect to which demands for appraisal have been received and the aggregate number of holders of such shares. If a petition for appraisal is duly filed by a stockholder and a copy of the petition is delivered to the surviving entity, the surviving entity will then be obligated within 20 days after receiving service of a copy of the petition to provide the Chancery Court with a duly verified list containing the names and addresses of all stockholders who have demanded an appraisal of their shares and with whom agreements as to the value of their shares have not been reached. After notice to dissenting stockholders, the Chancery Court is empowered to conduct a hearing upon the petition, to determine those stockholders who have complied with Section 262 and who have become entitled to the appraisal rights provided thereby. The Chancery Court may require the stockholders who have demanded payment for their shares to submit their stock certificates to the Register in Chancery Court may dismiss the proceedings as to such stockholder.

After determination of the stockholders entitled to appraisal of their shares of Valera common stock, the Chancery Court will appraise the shares, determining their fair value exclusive of any element of value arising from the accomplishment or expectation of the merger, together with a fair rate of interest, if any, to be paid. When the value is determined, the Chancery Court will direct the payment of such value, with interest thereon accrued during the pendency of the proceeding, if the Chancery Court so determines, to the stockholders entitled to receive the same, upon surrender by such holders of the certificates representing such shares.

In determining fair value, the Chancery Court is required to take into account all relevant factors. You should be aware that the fair value of your shares as determined under Section 262 could be more, the same, or less than the value that you are entitled to receive pursuant to the merger agreement. You also should be aware that investment banking opinions as to the fairness from a financial point of view of the consideration payable in the merger are not opinions as to fair value under Section 262.

Costs of the appraisal proceeding may be imposed upon the surviving entity and the stockholders participating in the appraisal proceeding by the Chancery Court as the Chancery Court deems equitable in the circumstances. Upon the application of a stockholder, the Chancery Court may order all or a portion of the expenses incurred by any stockholder in connection with the appraisal proceeding, including, without limitation, reasonable attorneys fees and the fees and expenses of experts, to be charged pro rata against the value of all shares entitled to appraisal. Any stockholder who had demanded appraisal rights will not, after the effective date of the merger, be entitled to vote shares subject to such demand for any purpose or to receive payments of dividends or any other distribution with respect to such shares (other than with respect to payment as of a record date prior to the effective date); however, if no petition for appraisal is filed within 120 days after the effective date of the merger, or if such stockholder delivers a written withdrawal of his or her demand for appraisal and an acceptance of the merger within 60 days after the effective date of the merger, then the right of such stockholder to appraisal will cease and such stockholder will be entitled to receive the shares of Indevus common stock and contingent stock rights for his or her shares of Valera common stock pursuant to the merger agreement. Notwithstanding the foregoing, no appraisal proceeding in the Chancery Court shall be dismissed as to any stockholder without the approval of the Chancery Court.

In view of the complexity of Section 262, Valera stockholders who may wish to dissent from the merger and pursue appraisal rights should consult their own legal advisors.

Failure to take any required step in connection with exercising appraisal rights may result in the termination or waiver of any appraisal rights.

# Resale of Indevus Common Stock Issued in Connection with the Merger; Affiliate Agreements

The shares of Indevus common stock to be issued in connection with the merger will be registered under the Securities Act and will be freely transferable under the Securities Act, except for shares issued to any person who is deemed to be an affiliate of Valera or Indevus at the time of its meeting. This joint proxy statement/prospectus does not cover resales of Indevus common stock issued in the merger by affiliates of Valera or Indevus. Valera has agreed to use reasonable efforts to cause each affiliate of Valera to execute an agreement whereby they agree not to transfer any shares of Indevus common stock received in the merger except in compliance with the Securities Act. Indevus has agreed to register the shares of Indevus common stock acquired by Sanders Morris Harris, Inc. (and affiliated entities) in connection with the merger for resale under the Securities Act on a Registration Statement on Form S-3 to be filed by Indevus within 30 days following the effective time of the merger. See the section entitled The Merger Agreement Covenants and Agreements Affiliate Agreements on page 124.

#### Delisting and Deregistration of Valera Common Stock Following the Merger

When the merger is completed, the Valera common stock currently listed on The Nasdaq Global Market will be delisted from The Nasdaq Global Market and deregistered under the Exchange Act.

# THE MERGER AGREEMENT

The following summary describes the material provisions of the merger agreement and is qualified in its entirety by reference to the merger agreement, a copy of which is included in this joint proxy statement/prospectus as Annex A and which we incorporate by reference into this joint proxy statement/prospectus. This summary may not contain all of the information about the merger agreement that is important to you. We encourage you to read the merger agreement carefully in its entirety because this document is the legal document governing the proposed merger.

The description of the merger agreement in this joint proxy statement/prospectus has been included to provide you with information regarding its terms, and we recommend that you read carefully the merger agreement in its entirety. Except for its status as the contractual document that establishes and governs the legal relations among the parties with respect to the merger, we do not intend for its text to be a source of factual, business or operational information about Indevus or Valera. That kind of information can be found elsewhere in this joint proxy statement/prospectus and in the documents incorporated herein by reference. The merger agreement contains representations and warranties of the parties as of specific dates and may have been used for the purposes of allocating risk between the parties other than establishing matters as facts. Those representations and warranties are qualified in several important respects, which you should consider as you read them in the merger agreement, including contractual standards of materiality that may be different from what may be viewed as material to stockholders. Only the parties themselves may enforce and rely on the terms of the merger agreement. As stockholders, you are not third party beneficiaries of the merger agreement and therefore may not directly enforce or rely upon its terms and conditions and you should not rely on its representations, warranties or covenants as characterizations of the actual state of facts or condition of Indevus, Valera, Hayden Merger Sub, Inc. or any of their respective affiliates. Moreover, information concerning the subject matter of the representations and warranties may have changed since the date of the merger agreement and subsequently developed or new information qualifying a representation or warranty may have been included in this joint proxy statement/prospectus.

# The Merger

#### Generally

Upon the terms and subject to the conditions set forth in the merger agreement, Hayden Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Indevus, which was formed for the sole purpose of effectuating the merger and which we refer to as Merger Sub, will be merged with and into Valera. As a result of the merger, Merger Sub s corporate existence will cease and Valera will be the surviving corporation and will become a wholly-owned subsidiary of Indevus. Each issued and outstanding share of common stock of Merger Sub will be converted into one fully paid and non-assessable share of the surviving corporation. The separate corporate existence of Valera will continue unaffected by the merger, except as set forth in the merger agreement. The name of the surviving corporation initially will be Valera Pharmaceuticals, Inc.

# Certificate of Incorporation and Bylaws of Surviving Corporation

The certificate of incorporation and bylaws of Valera in effect immediately prior to the effective time of the merger will be the certificate of incorporation and bylaws of the surviving corporation until thereafter changed or amended under applicable law.

# Directors and Officers of the Surviving Corporation after the Merger

The directors of the surviving corporation will be the directors of Merger Sub immediately prior to the closing of the merger until the earlier of their resignation or removal or until their respective successors are duly designated, as the case may be. The initial officers of the surviving corporation will be the officers of Valera

immediately prior to the closing of the merger until the earlier of their resignation or removal or until their respective successors are duly designated, as the case may be.

#### **Closing and Effectiveness of the Merger**

Unless the parties agree otherwise, the closing of the merger will take place on a date specified by the parties, but no later than the third business day after all closing conditions have been satisfied or waived, at the offices of Skadden, Arps, Slate, Meagher & Flom LLP, Four Times Square, New York, New York 10036. The merger will become effective when we file a certificate of merger with the Delaware Secretary of State, unless we agree to a later time for the completion of the merger and specify that time in the certificate of merger. See Conditions to Completion of the Merger below for a more complete description of the conditions that must be satisfied or waived prior to the closing.

We currently expect that the merger will be completed in the second calendar quarter of 2007 shortly after the occurrence of the Indevus and Valera stockholder meetings. However, because completion of the merger is subject to regulatory approvals and other conditions, neither Indevus nor Valera can assure you when or if the merger will occur.

#### **Merger Consideration**

#### Exchange Ratio and Conversion of Valera Common Stock

At the effective time of the merger, each then-outstanding share of Valera common stock (excluding shares for which dissenters rights have been properly exercised) will be converted into the right to receive Indevus common stock according to an exchange ratio (described below) and three contingent stock rights (see Contingent Stock Rights below).

The merger agreement provides that, at the effective time of the merger:

Each share of Valera common stock issued and outstanding immediately prior to the merger will be automatically canceled and will cease to exist, and will automatically be converted into the right to receive a number of shares of Indevus common stock based on an exchange ratio determined prior to the Valera stockholders meeting. This exchange ratio will be determined by dividing \$7.75 by the volume weighted average of the closing prices of Indevus common stock, which we refer to as the Indevus Common Stock Value, as reported by The Nasdaq Global Market during the 25 trading days ending five trading days prior to the date of the Valera stockholders meeting. The exchange ratio is subject to a collar and will range from a minimum of 0.9626 to a maximum of 1.1766 of a share of Indevus common stock, as follows:

if the Indevus Common Stock Value is \$6.59 or more but not greater than \$8.05, then the exchange ratio will be determined by dividing \$7.75 by the Indevus Common Stock Value (and will be calculated to the nearest one ten-thousandth share of Indevus common stock);

if the Indevus Common Stock Value is less than \$6.59, then the exchange ratio will be fixed at 1.1766 shares of Indevus common stock for each share of Valera common stock; and

if the Indevus Common Stock Value is greater than \$8.05, then the exchange ratio will be fixed at 0.9626 of a share of Indevus common stock for each share of Valera common stock.

# **Contingent Stock Rights**

In addition to the shares of Indevus common stock as provided above, and subject to the terms and conditions set forth in contingent stock rights agreements to be entered into between Indevus and a rights agent, for each share of Valera common stock Valera stockholders also will receive three contingent stock rights, which we refer to as CSRs. Each CSR relates to one of three Valera products in development Supprelin-LA, the

ureteral stent and VP003 (Octreotide implant). See the section entitled The Contingent Stock Rights Agreements beginning on page 132 for a description of the material terms of the CSRs and the forms of contingent stock rights agreements to be entered into.

Upon the achievement of the applicable milestones approval of the particular product by the U.S. Food and Drug Administration, or the FDA, and, in the case of Supprelin-LA, Indevus possessing a specified amount of inventory of commercially saleable units the CSRs relating to Supprelin-LA, the ureteral stent and VP003 (Octreotide implant) will become convertible into \$1.00, \$1.00 and \$1.50, respectively, worth of Indevus common stock calculated using the average of the per share closing sale prices of Indevus common stock as reported by Nasdaq for the ten trading days ending three trading days prior to achieving the applicable milestone or milestones. If the applicable milestone or milestones are not achieved within three years of completing the merger in the case of Supprelin-LA and within five years of completing the merger in the case of the ureteral stent and VP003 (Octreotide implant), the respective CSRs will expire and no shares of Indevus common stock will be issued in connection with those CSRs.

Additionally, the aggregate amount of Indevus common stock to be issued pursuant to the CSRs is subject to a limit and may not exceed the number of shares of Indevus common stock issued as part of the merger consideration provided at the effective time of the merger.

# No Fractional Shares

Indevus will not issue any fractional shares of its common stock in the merger. Each holder of Valera common stock exchanged in the merger who would otherwise be entitled to receive a fraction of a share of Indevus common stock will receive an amount of cash, without interest, determined by multiplying the fractional share interest by the Indevus Common Stock Value.

#### **Treatment of Valera Options**

Upon the closing of the merger, each outstanding option to purchase shares of Valera common stock will be cancelled in exchange for the right to receive the following consideration:

Option holders that consent to the proposed treatment of Valera options will receive the following with respect to each share of Valera common stock underlying the option:

Options with a per share exercise price below \$7.75 will receive (i) at closing, a number of shares of Indevus common stock equal to (x) the excess of \$7.75 over the per share exercise price of the option divided by (y) the Indevus Common Stock Value (but not less than \$6.59 nor more than \$8.05); and (ii) Indevus unfunded and unsecured promise to issue, in the future, the number of shares of Indevus common stock that would have been issuable had option holders received CSRs.

Options with a per share exercise price of \$7.75 or greater will receive Indevus unfunded and unsecured promise to issue, in the future, a number of shares of Indevus common stock determined by a formula intended to provide value equivalent to the CSRs, net of the option exercise price exceeding \$7.75.

Option holders that do not provide consent to the proposed treatment of Valera options will receive the following:

Options with a per share exercise price below the closing price of Valera common stock on the trading day immediately preceding the closing of the merger will receive shares of Indevus common stock based on the spread between Valera s closing stock price on the trading day immediately preceding the closing of the merger and the exercise price of the option, but will not receive CSRs.

Options with a per share exercise price equal to or greater than the closing price of Valera common stock on the trading day immediately preceding the closing of the merger will not be entitled to any consideration upon cancellation.

Cash will be paid to Valera option holders, without interest, in lieu of any fractional shares of Indevus common stock an option holder would otherwise be entitled to receive. All consideration paid to option holders shall be subject to the withholding of all federal, state, local or foreign taxes in accordance with applicable law.

# Exchange of Valera Stock Certificates; No Further Rights as Valera Stockholders

At or prior to the closing of the merger, Indevus will engage a nationally-recognized financial institution reasonably satisfactory to Valera to act as exchange agent in connection with the merger. Promptly following the closing of the merger, the exchange agent will mail to each record holder of Valera common stock a letter of transmittal. The letter of transmittal will contain instructions explaining the procedure for surrendering Valera common stock certificates in exchange for the merger consideration.

Valera stockholders who surrender their stock certificates, together with the properly completed letter of transmittal and any other documents as may reasonably be required by the exchange agent, will be entitled to receive:

the number of shares of Indevus common stock (which shares will be in uncertificated book-entry form unless a physical certificate is requested by the holder) into which those shares of Valera common stock have been converted;

cash in lieu of any fractional share of Indevus common stock;

uncertificated book-entries representing one contingent stock right for each of Supprelin-LA, the ureteral stent and VP003 (Octreotide implant) for each share of Valera common stock surrendered; and

dividends or other distributions, if any, declared or made after completion of the merger on Indevus common stock, which Valera stockholders are entitled to under the terms of the merger agreement.

In the event of a transfer of ownership of Valera common stock that is not registered in the transfer records of Valera, the proper number of shares of Indevus common stock may be issued to a person other than the person in whose name the certificate so surrendered is registered if the certificate is properly endorsed or otherwise in proper form for transfer and the person requesting the issuance will pay any transfer or other taxes required by reason of the issuance of shares of Indevus common stock to a person other than the registered holder of the certificate or establish to the satisfaction of Indevus that the tax has been paid or is not applicable.

After the closing of the merger, each certificate representing shares of Valera common stock that has not been surrendered will represent only the right to receive upon surrender of that certificate the consideration identified above. The surrendered certificates representing Valera common stock will be canceled.

# Holders of Valera common stock should not send in their Valera stock certificates until they receive a letter of transmittal from the exchange agent, with instructions for the surrender of Valera stock certificates.

# Distributions with Respect to Unexchanged Shares

Holders of Valera common stock are not entitled to receive any dividends or other distributions on Indevus common stock until the merger is completed. After the merger is completed, holders of Valera stock certificates will be entitled to dividends and other distributions declared or made after completion of the merger with respect to the number of whole Indevus common stock which they are entitled to receive upon exchange of their Valera stock certificates, but they will not be paid any dividends or other distributions on the Indevus common stock until they surrender their Valera stock certificates to the exchange agent in accordance with the exchange agent instructions.

#### **Representations and Warranties**

Valera made customary representations and warranties in the merger agreement, on behalf of itself, and its subsidiaries, and Indevus made customary representations and warranties in the merger agreement, on behalf of itself and its subsidiaries. These representations are subject, in some cases, to specified exceptions and qualifications contained in the merger agreement or in information provided pursuant to certain disclosure obligations set forth in the merger agreement. Some of the representations and warranties are qualified as to materiality or material adverse effect.

For the definition of material adverse effect see Material Adverse Effect beginning on page 118.

#### Representations and Warranties by Valera

Valera s representations and warranties relate to, among other things:

corporate organization, qualification to do business and good standing of Valera and its subsidiaries;

capital structure of Valera and its subsidiaries;

corporate authority of Valera to enter into the merger agreement and to consummate the transactions contemplated by the merger agreement;

determination by Valera s board of directors that the transactions under the merger agreement are advisable and in the best interests of Valera and its stockholders, the recommendation by Valera s board that its stockholders vote in favor of adoption of the merger agreement, and the voting requirements relating to, the merger agreement;

receipt by Valera s board of directors of an opinion from Valera s financial advisor, to the effect that, as of the date of the merger agreement, the merger consideration was fair from a financial point of view to the holders of Valera common stock;

absence of conflicts with organizational documents, laws or agreements as a result of entering into and consummating the merger and the other transactions contemplated by the merger agreement;

absence of need for filings with and consents of governmental authorities;

holding of, and compliance with, the permits, licenses, franchises, authorizations and approvals from governmental entities and other regulatory agencies necessary for the operation of the businesses and products and services of Valera and its subsidiaries;

proper filing of documents with the SEC and the accuracy of information, including financial information, contained in these documents; conformity with GAAP of Valera s financial statements filed with the SEC;

compliance with the Sarbanes-Oxley Act of 2002 and other corporate governance matters, including the maintenance of internal control over financial reporting and other required disclosures;

absence of undisclosed liabilities related to Valera and its subsidiaries;

absence of certain adverse changes to Valera or its subsidiaries since December 31, 2005;

compliance with applicable laws, including laws governing the marketing, sale, use, safety, efficacy, reliability or manufacturing of drug or biological products or medical devices, and possession of permits required to conduct the business of Valera and its subsidiaries;

tax matters;

change of control agreements;

absence of any material undisclosed litigation, investigation or injunction;

validity and enforceability of material contracts of Valera and its subsidiaries and the absence of material violations or defaults under material contracts;

employee benefit plans;

labor and employment matters;

compliance with applicable environmental laws and the absence of environmental liabilities;

matters relating to the intellectual property of Valera and its subsidiaries;

absence of any stockholders rights agreement or any similar plan or agreement which limits or impairs the ability of Indevus to purchase, or become the direct or indirect beneficial owner of the securities of Valera or its subsidiaries;

absence of brokers fees in connection with the merger; and

#### insurance. Representations and Warranties by Indevus

Indevus representations and warranties relate to, among other things:

corporate organization, qualification to do business and good standing of Indevus and its subsidiaries;

capital structure of Indevus and its subsidiaries;

corporate authority of Indevus to enter into the merger agreement and the other ancillary agreements and to consummate the transactions contemplated by these agreements;

determination by Indevus board of directors that the transactions contemplated by the merger agreement are fair to and in the best interests of Indevus and its stockholders, the recommendation by Indevus board that its stockholders vote in favor of approval of the issuance of Indevus common stock and contingent stock rights pursuant to the merger agreement;

receipt by Indevus board of directors of an opinion from Indevus financial advisor;

absence of conflicts with organizational documents, laws or agreements as a result of entering into and consummating the merger and the other transactions contemplated by the merger agreement;

absence of need for filings with and consents of governmental authorities;

holding of, and compliance with, the permits, licenses, franchises, authorizations and approvals from governmental entities and other regulatory agencies necessary for the operation of the businesses;

proper filing of documents with the SEC and the accuracy of information, including financial information, contained in these documents; conformity with GAAP of Indevus financial statements filed with the SEC;

compliance with the Sarbanes-Oxley Act of 2002 and other corporate governance matters, including the maintenance of internal control over financial reporting and other required disclosures;

absence of undisclosed liabilities related to Indevus and its subsidiaries;

absence of certain adverse changes to Indevus or its subsidiaries since September 30, 2006;

compliance with applicable laws, including laws governing the marketing, sale, use, safety, efficacy, reliability or manufacturing of drug or biological products or medical devices, and possession of permits required to conduct the business of Indevus and its subsidiaries;

tax matters;

absence of any material undisclosed litigation, investigation or injunction;

validity and enforceability of material contracts of Indevus and its subsidiaries and the absence of or material violations or defaults under material contracts;

employee benefit plans;

compliance with applicable environmental laws and the absence of environmental liabilities;

matters relating to the intellectual property of Indevus and its subsidiaries;

absence of any stockholders rights agreement or any similar plan or agreement which limits or impairs the ability to purchase, or become the direct or indirect beneficial owner of the securities of Indevus or its subsidiaries; and

absence of brokers fees relating to the transaction. Material Adverse Effect

Any reference to material adverse effect, when used in connection with Indevus or Valera (including the surviving corporation as the successor to Valera) means any change, effect, event, occurrence, state of facts or development which individually or in the aggregate, results in any change or effect that is materially adverse to the business, financial condition, properties, assets, liabilities (contingent or otherwise) or results of operations of the person and its subsidiaries, taken as a whole, or prevents or materially impedes, interferes with, hinders or delays the consummation by Indevus or Valera, as applicable, of the merger or the other transactions contemplated by the merger agreement. However, none of the following are deemed, either alone or in combination, to constitute, and none of the following are to be taken into account in determining whether there has been or will be, a material adverse effect:

any change relating to the economy or securities markets in general;

any adverse change, effect, event, occurrence, state of facts or development attributable to conditions affecting the industry in which Indevus or Valera, as applicable, participates, including any changes to reimbursement rates related to any Valera products, so long as the effects of any of the foregoing do not disproportionately impact Indevus or Valera, as applicable;

any decline in Indevus or Valera s net sales after the date of the merger agreement;

any failure, in and of itself, by Indevus or Valera s to meet any internal or published projections, forecasts or revenue or earnings predictions for any period ending on or after the date of the merger agreement;

the effect of any change in any applicable law or GAAP; or

any events or occurrences directly or indirectly related to the impact of the merger agreement (or the merger) or the announcement or performance of the merger agreement (or the merger) or the transactions contemplated by the merger agreement (or the merger). In addition, Valera s receipt of a nonapprovable letter with regard to Supprelin-LA, taken alone, will not constitute a material adverse effect on Valera.

#### **Covenants and Agreements**

**Restrictions on the Interim Operations of Valera** 

Valera has agreed that, during the period from the date of the merger agreement and the earlier of the completion of the merger or the termination of the merger agreement, it will, and will cause its subsidiaries to, conduct their respective businesses in the ordinary course consistent with past practice and to use its commercially reasonable best efforts to:

preserve intact its business organization;

preserve its assets and properties in good repair and condition;

keep available the services of its current officers and employees and to preserve; and

preserve, in all material respects, the current relationships with its customers, suppliers, licensors, licensees, distributors and other persons with which it has business dealings.

Valera has further agreed that, during the same time period, subject to specified exceptions or unless Indevus has given prior written consent (consent not to be unreasonably withheld or delayed), Valera will not, and will cause its subsidiaries not to, among other things:

amend its organizational documents;

declare or pay any dividends on or make other distributions (whether in cash, stock or property) in respect of any of its capital stock;

subdivide, reclassify, recapitalize, split, combine or exchange or enter into any similar transaction with respect to any of its capital stock or issue or authorize or propose the issuance of any other securities in respect of, in lieu of or in substitution for shares of its capital stock;

repurchase, redeem or otherwise acquire any shares of its capital stock or any stock rights;

issue, deliver or sell, or authorize, propose or reserve for issuance, delivery or sale, or otherwise encumber, any shares of its capital stock or stock rights, other than the issuance of shares upon the exercise of stock options, in each case outstanding on the date of the merger agreement in accordance with their present terms;

create, assume or incur any indebtedness for borrowed money or guaranty any indebtedness of another person, or repay, redeem or repurchase any indebtedness, other than in the ordinary course of business consistent with past practices;

make any loans, advances or capital contributions to, or any investments in, any other person;

sell, assign, lease, license, sell and leaseback, mortgage, pledge or otherwise encumber or dispose of any assets or properties that are material, individually or in the aggregate, to Valera and its subsidiaries, taken as a whole;

enter into, modify or amend any lease of property, except for modifications or amendments that are not adverse to the surviving corporation after the merger;

directly or indirectly acquire (i) by merging or consolidating with, or by purchasing assets of, or by any other manner, any division, business or equity interest of any person (including in a transaction involving a tender or exchange offer, business combination, recapitalization, liquidation, dissolution, joint venture or similar transaction) or (ii) any material assets;

implement or adopt any material change in its accounting policies other than as may be required by applicable law or GAAP and as concurred with by Valera s independent auditors;

except to the minimum extent required in order to comply with applicable law or to the minimum extent required in order to avoid adverse treatment under Section 409A of the Code: (i) amend any of the terms or conditions of employment for any of its directors or officers, (ii) adopt, enter into, terminate or amend any benefit plan, benefit agreement or collective bargaining agreement, other than amendments that are immaterial or administrative in nature, (iii) increase in any manner the compensation or benefits of, or pay any bonus to, any participant, other than annual salary increases and target bonuses to be paid to employees in the ordinary course of

business consistent with past practice, (iv) grant any awards under any benefit plan (including the grant of stock options, stock appreciation rights, performance units, restricted stock, deferred stock awards, stock purchase rights or other stock-based or stock-related awards) or remove or modify existing restrictions in any benefit plan or benefit agreement on any awards made thereunder, (v) take any action to accelerate the vesting or payment of any compensation or benefits under any contract, benefit plan or benefit agreement or (vi) make any material determination under any benefit plan or benefit agreement that is inconsistent with the ordinary course of business or past practice;

modify or amend in any material respect or terminate or cancel or waive, release or assign any material rights or claims with respect to, any material contract or enter into any agreement or contract that would qualify as a material contract;

enter into any contract relating to the development or commercialization of any pharmaceutical product, including but not limited to licensing, development, manufacturing, co-development, marketing or co-marketing agreements, other than development, manufacturing and marketing agreements entered into the ordinary course of business consistent with past practice;

pay, loan or advance (other than the payment of compensation, directors fees or reimbursement of expenses in the ordinary course of business) any amount to, or sell, transfer or lease any properties or assets (real, personal or mixed, tangible or intangible) to, or enter into any agreement with, any of its officers or directors or any affiliate or associate of any of its officers or directors;

form or commence the operations of any business or any corporation, partnership, joint venture, business association or other business organization or division thereof (other than in the ordinary course of business consistent with past practice) or enter into any new line of business that is material to Valera and its subsidiaries, taken as a whole;

make any material tax election or settle or compromise any material tax liability or refund;

pay, discharge, settle or satisfy any claims, litigation, liabilities or obligations (whether absolute, accrued, asserted or unasserted, contingent or otherwise), other than the payment, discharge, settlement or satisfaction, in the ordinary course of business consistent with past practice or in accordance with their terms, of liabilities: (A) reflected or reserved against in, or contemplated by, the most recent consolidated financial statements (or the notes thereto) included in the SEC reports filed by Valera or (B) incurred in the ordinary course of business consistent with past practice or, (ii) cancel any material indebtedness (individually or in the aggregate) or waive any claims or rights of substantial value;

make or agree to make any new capital expenditure or expenditures which, individually, are in excess of \$100,000 or, in the aggregate, are in excess of \$250,000;

fail to take any action necessary or advisable to protect or maintain the intellectual property that is material to the conduct of Valera s business as currently conducted and planned to be conducted, including the prosecution of all pending applications for patents and trademarks, the filing of any documents or other information or the payment of any maintenance or other fees related thereto; or

authorize, or commit or agree to take, any of the foregoing actions. *Restrictions on the Interim Operations of Indevus* 

Indevus has agreed that, during the period from the date of the merger agreement and the earlier of the completion of the merger or the termination of the merger agreement, subject to specified exceptions or unless Indevus has given prior written consent (consent not to be unreasonably withheld or delayed), Indevus will not, and will cause its subsidiaries not to, among other things:

amend its certificate of incorporation or the bylaws, except for amendments that do not impact its capital structure;

declare or pay any dividends on or make other distributions (whether in cash, stock or property) in respect of any of its capital stock;

subdivide, reclassify, recapitalize, split, combine or exchange or enter into any similar transaction with respect to any of its capital stock or issue or authorize or propose the issuance of any other securities in respect of, in lieu of or in substitution for shares of its capital stock;

repurchase, redeem or otherwise acquire any shares of its capital stock or any stock rights, other than in connection with (i) the redemption of its convertible senior notes due July 2008 or the conversion of its Series B convertible preferred stock or Series C convertible preferred stock, (ii) the forfeiture or expiration of outstanding Indevus options and (iii) the withholding of shares of Indevus common stock to satisfy tax obligations with respect to the exercise of Indevus options pursuant to any obligations contained in its stock plans;

issue, deliver or sell, or authorize, propose or reserve for issuance, delivery or sale of, or otherwise encumber any shares of its capital stock or any stock rights, other than (i) the issuance of shares upon the exercise of Indevus options outstanding on December 11, 2006 in accordance with their present terms, (ii) the issuance of shares upon conversion of Series B convertible preferred stock or Series C convertible preferred stock, (iii) issuances of up to 12,000,000 shares of capital stock in the aggregate (excluding shares described in clauses (i) and (ii)) and (iv) the issuance of up to \$50 million in debt securities convertible into shares of Indevus capital stock;

create, assume or incur any indebtedness for borrowed money or guaranty any indebtedness of another person, or repay, redeem or repurchase any indebtedness, other than (i) in the ordinary course of business consistent with past practices, (ii) for the purpose of refinancing any existing indebtedness, (iii) the issuance of up to \$50 million in debt securities convertible into shares of Indevus capital stock and (iv) the incurrence of additional indebtedness of up to \$10 million, in the aggregate (excluding indebtedness described in clauses (i), (ii) and (iii));

sell, assign, lease, license, sell and leaseback, mortgage, pledge or otherwise encumber or dispose of any Indevus product that is material, individually or in the aggregate, to Indevus and its subsidiaries, taken as a whole; or

authorize, or commit or agree to take, any of the foregoing actions *No Solicitation by Valera* 

Subject to certain provisions regarding a Superior Proposal (as defined below), the merger agreement provides that Valera may not, nor may it authorize or permit any of its subsidiaries or its or their representatives to, directly or indirectly:

solicit, initiate or encourage, or take any other action designed to, or which is reasonably expected to, facilitate, any Takeover Proposal (as defined below);

enter into any agreement with respect to any Takeover Proposal; or

enter into, continue or otherwise participate in any discussions or negotiations regarding, or furnish to any person any information with respect to, or otherwise cooperate with, any proposal that constitutes, or is reasonably expected to lead to, any Takeover Proposal.

The merger agreement also provides that Valera will, and will cause its subsidiaries and its representatives to, terminate all discussions or negotiations existing as of the date of the merger agreement with any person with respect to any proposal that constitutes, or is reasonably expected to lead to, any Takeover Proposal and request the prompt return or destruction of all confidential information previously furnished.

The term **Takeover Proposal** means, other than the transactions contemplated by the merger agreement:

any inquiry, proposal or offer from any person, relating to, or that is reasonably expected to lead to, any direct or indirect acquisition or purchase, in one transaction or a series of transactions, of assets or businesses that constitute (i) 15% or more of the revenues, net income, EBITDA (earnings before interest expense, taxes, depreciation and amortization) or the assets of Valera and its subsidiaries, taken as a whole, or (ii) 15% or more of any class of equity securities of Valera or any of its subsidiaries;

any tender offer or exchange offer that if consummated would result in any person beneficially owning 15% or more of any class of equity securities of Valera or any of its subsidiaries; or

any merger, consolidation, business combination, recapitalization, liquidation, dissolution, joint venture, binding share exchange or similar transaction involving Valera or any of its subsidiaries pursuant to which any person or the stockholders of any person would own 15% or more of any class of equity securities of Valera or any of its subsidiaries or of any resulting parent company of Valera.

The merger agreement also requires that Valera promptly advise Indevus orally and in writing (and in any case within 24 hours), of any Takeover Proposal or any inquiry that is reasonably expected to lead to any Takeover Proposal, the material terms and conditions of any Takeover Proposal or inquiry (including the status, details and any changes thereto) and the identity of the person making the Takeover Proposal or inquiry along with copies of any related correspondence.

The merger agreement also provides that at any time prior to obtaining the approval of the merger by Valera stockholders, in response to a bona fide written Takeover Proposal that Valera s board of directors determines (after consultation with outside counsel and a financial advisor of nationally recognized reputation) constitutes, or is reasonably expected to lead to, a Superior Proposal (as defined below), and which Takeover Proposal was not solicited after the date of the merger agreement, was made after the date of the merger agreement and did not otherwise result from a breach of the merger agreement, Valera may, if a majority of its board of directors determines (after receiving the advice of outside counsel) that it is necessary to take these actions in order to comply with its fiduciary duties to the stockholders of Valera under applicable law, and subject to compliance with the merger agreement and after giving Indevus written notice of this determination:

furnish information with respect to Valera and its subsidiaries to the person making the Takeover Proposal (and its representatives) pursuant to a customary confidentiality agreement meeting requirements set forth in the merger agreement; and

participate in discussions or negotiations with the person making the Takeover Proposal (and its representatives) regarding the Takeover Proposal.

The term *Superior Proposal* means a bona fide Takeover Proposal (as defined above, provided however that 50% should be substituted for all references to 15% in the definition above) which Valera s board of directors determines in good faith (after consultation with outside counsel and a financial advisor of nationally recognized reputation) to be (i) more favorable to the stockholders of the Valera from a financial point of view than the merger, taking into account all relevant factors (including all of the terms and conditions of the proposal and the merger agreement, including any changes to the terms of the merger agreement proposed by Indevus in response to the offer or otherwise) and (ii) reasonably capable of being completed, taking into account all financial, legal, regulatory and other aspects of the proposal.

#### Valera Board of Directors Covenant to Recommend

The merger agreement provides that neither Valera's board of directors nor any committee of Valera's board of directors may adopt, approve, recommend or declare advisable, or allow Valera or any of its subsidiaries to execute or enter into, any letter of intent, memorandum of understanding, agreement in principle, merger agreement, acquisition agreement, option agreement, joint venture agreement, partnership agreement or other similar agreement constituting or related to, or that is intended to or is reasonably expected to lead to, any Takeover Proposal (other than a confidentiality agreement permitted by the merger agreement).

The merger agreement also provides that neither Valera s board of directors nor any committee of Valera s board of directors may:

withdraw (or qualify or modify in a manner adverse to Indevus or Merger Sub), or publicly propose to withdraw (or qualify or modify in a manner adverse to Indevus or Merger Sub), the adoption, approval, recommendation or declaration of advisability by Valera s board of directors or any committee of Valera s board of directors of the merger agreement, or the other transactions contemplated by the merger agreement; or

recommend, adopt, approve or declare advisable, or propose publicly to recommend, adopt, approve or declare advisable, any Takeover Proposal.

However, at any time prior to obtaining the approval of the merger by Valera stockholders, if a majority of Valera s board of directors determines (after receiving the advice of outside counsel) that it is necessary to take

these actions in order to comply with its fiduciary duties to Valera stockholders under applicable law, Valera s board of directors may take these actions after the fifth calendar day following Indevus receipt of written notice from Valera advising Indevus that Valera s board of directors intends to take these actions and specifying the reasons for taking the actions, including the terms and conditions of any Superior Proposal that is the basis of the proposed action.

#### Indevus Board of Directors Covenant to Recommend

The merger agreement provides that neither Indevus board of directors nor any committee of Indevus board of directors may withdraw (or qualify or modify in a manner adverse to Valera), or publicly propose to withdraw (or qualify or modify in a manner adverse to Valera), the adoption, approval, recommendation or declaration of advisability by Indevus board of directors or any committee of Indevus board of directors of the merger agreement, or the other transactions contemplated by the merger agreement. However, at any time prior to obtaining the approval of the merger by Indevus stockholders, if a majority of Indevus board of directors determines (after receiving the advice of outside counsel) that it is necessary to take these actions in order to comply with its fiduciary duties to Indevus stockholders under applicable law, Indevus board of directors may take these actions after the fifth calendar day following Valera s receipt of written notice from Indevus advising Valera that Indevus board of directors intends to take the actions and specifying the reasons for taking the actions.

#### Antitrust Filings

Each of Valera and Indevus agree to:

make or cause to be made, to the extent applicable and as promptly as practicable, an appropriate filing of a Notification and Report Form pursuant to the HSR Act with respect to the transactions contemplated by the merger agreement and all other necessary filings, forms, declarations, notifications, registrations and notices with other governmental entities under competition laws relating to the transactions contemplated by the merger agreement (each of Valera and Indevus filed its respective Notification and Report Form on January 16, 2007);

use reasonable best efforts to respond at the earliest practicable date to any requests for additional information from the United States Department of Justice or any other governmental entities and act in good faith and reasonably cooperate with the other party in connection with any investigation by any governmental entity;

use reasonable best efforts to furnish to each other all information required for any filing, form, declaration, notification, registration and notice;

give the other party reasonable prior notice of any communication with, and any proposed understanding or agreement with, any governmental entity regarding any filings, forms, declarations, notifications, registrations or notices, and permit the other to review and discuss in advance, and consider in good faith the views of the other in connection with, any proposed communication, understanding or agreement with any governmental entity with respect to the transactions contemplated by the merger agreement;

not independently participate in any meeting or engage in any substantive conversation with any governmental authority with respect to any filings or inquiry without giving the other party prior notice of the meeting and, unless prohibited by the governmental entity, the opportunity to attend and/or participate in any meeting or substantive conversation; and

consult and cooperate with one another in connection with any information or proposals submitted in connection with proceedings under any antitrust laws.

Each of Valera and Indevus agree to use its reasonable best efforts (i) to avoid the entry of any judgment that would restrain, prevent or delay the closing of the merger; (ii) to eliminate every impediment under any

antitrust laws that may be asserted by any governmental entity so as to enable the closing to occur as soon as reasonably possible (and in any event no later than August 11, 2007); and (iii) vigorously to contest and resist these actions or proceedings, including any administrative or judicial actions.

Notwithstanding anything to the contrary in the merger agreement, neither Valera nor Indevus will be required in order to resolve any objections asserted under antitrust laws by any governmental entity with respect to the transactions contemplated by the merger agreement to divest any of its businesses, product lines or assets, or take or agree to take any other action or agree to any limitation or restriction, that is reasonably likely to result in a material adverse effect on Valera or Indevus, respectively (provided that, in the case of Indevus, the determination will be made after giving effect to the merger).

#### Affiliate Agreements

Valera agrees to use reasonable best efforts to cause each affiliate of Valera to enter into an agreement with Valera and Indevus not less than 30 days prior to the effective time of the merger, pursuant to which, among other things, the person will acknowledge the application of Rule 145 under the Securities Act and other SEC rules and regulations to certain resales of the shares of Indevus common stock to be received and held as a result of the merger and the other transactions contemplated in the merger agreement. Indevus will be entitled to place appropriate legends on the certificates evidencing any Indevus common stock to be received by an affiliate of Valera in the merger.

#### **Employees and Employee Benefit Matters**

For a period of one year following the closing of the merger, Indevus will or will cause the surviving corporation to either:

provide the employees of Valera and its subsidiaries who are employed immediately prior to the closing of the merger who remain employed during this one year period by Indevus, the surviving corporation or any of their respective subsidiaries with compensation and benefits (excluding equity based compensation) which have a value substantially comparable, in the aggregate, to the compensation and benefits provided by Valera and its subsidiaries as of the date of the merger agreement; or

provide or cause the surviving corporation (or, in this case, its successors or assigns) to provide employees of Valera and its subsidiaries who are employed immediately prior to the closing of the merger who remain employed during this one year period by Indevus, the surviving corporation or their respective subsidiaries with compensation and benefits that, taken as a whole, are not materially less favorable in the aggregate to these employees than those provided to similarly situated employees of Indevus and its subsidiaries.

In connection with the merger, Indevus will waive all limitations on preexisting conditions or waiting periods with respect to participation and coverage requirements applicable to the Valera employees under any welfare benefit plans that the employees may be eligible to participate. Indevus has also agreed to provide each Valera employee with credit for any co-payments and deductibles paid under any Valera benefit plan that provides healthcare benefits in the plan year in effect as of the closing in satisfying any applicable deductible or out-of-pocket expenses under any healthcare plans of Indevus.

#### **Product Development Efforts**

After the completion of the merger, Indevus has agreed to use commercially reasonable efforts to develop, in the ordinary course, Supprelin-LA, the ureteral stent and VP003 (Octreotide implant); provided, that, with respect to Supprelin, Indevus obligations will terminate on the third anniversary of completing the merger, and with respect to the ureteral stent and Octreotide, Indevus obligations will terminate on the fifth anniversary of

completing the merger. For purposes of the merger agreement, commercially reasonable efforts means efforts and resources normally used by Indevus for a product owned by it or to which it has exclusive rights, which is of similar market potential at a similar stage in its development or product life, taking into account issues of safety and efficacy, product profile, competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory and reimbursement structure involved, the profitability of the applicable products, and other relevant factors.

#### Transition Committee

Valera and Indevus will establish a joint transition management committee consisting of two representatives from each company. The transition committee will be responsible for organizing, developing, managing and implementing a transition plan for the prompt and efficient integration of the business organizations of the companies subject to the requirement that control of the management, properties and assets of Indevus and Valera will at all times prior to the closing of the merger remain under the control of their respective board of directors.

#### Other Covenants and Agreements.

The merger agreement contains certain other covenants and agreements, including covenants relating to:

cooperation between Valera and Indevus in the preparation of this joint proxy/prospectus;

the recommendations of the companies boards of directors that stockholders vote in favor of the merger proposals and the timeliness in holding stockholders meetings to consider approval of the merger proposals;

access by Indevus to certain business, properties, litigation, personnel and other information about Valera prior to the closing of the merger;

the confidentiality of all non-public information provided by the other party;

development of a joint communications strategy with respect to any public statements regarding the merger;

each party s obligation to provide prompt notice to the other party of the following:

material breaches of representations, warranties or covenants contained in the merger agreement; and

any material adverse effect;

Valera s obligation to provide prompt notice to Indevus of communications from any regulatory authority and material communications from any person relating to Valera intellectual property;

Indevus obligation to provide prompt notice to Valera of material communications from any regulatory authority;

the taking of any action, or the failure to take any action, that would reasonably be expected to jeopardize the qualification of the merger as a tax-free reorganization;

Indevus using its reasonable best efforts to cause the Indevus common stock to be issued or issuable pursuant to the merger agreement to be approved for listing on The Nasdaq Global Market; and

each party bearing its own expenses incurred in connection with the merger, the merger agreement and the transactions contemplated by the merger agreement, except that each of Valera and Indevus shall bear and pay one-half of the costs and expenses incurred in connection with filing, printing and mailing this document.

#### Conditions to Completion of the Merger

#### Conditions to the Obligations of Indevus, Merger Sub and Valera

The respective obligations of Indevus, Merger Sub and Valera to complete the merger are subject to the satisfaction or waiver of the following conditions:

adoption of the merger agreement by Valera stockholders;

approval of the issuance of Indevus common stock and contingent stock rights in connection with the merger by Indevus stockholders;

no judgment or other legal prohibition of any court or other governmental entity shall be in effect that prohibits the completion of the merger;

the SEC having declared effective the registration statement of which this document forms a part;

authorization for listing on The Nasdaq Global Market of the shares of Indevus common stock issuable to Valera stockholders in the merger;

termination or expiration of the applicable waiting periods under the HSR Act and any other applicable foreign antitrust, competition or similar law; and

absence of any suit, action or proceeding by any governmental entity which challenges or seeks to enjoin the merger or the other transactions contemplated by the merger agreement.

In addition, the respective obligations of Indevus, Merger Sub and Valera to complete the merger are subject to the satisfaction or waiver of the following additional conditions:

the representations and warranties of the other party qualified by material adverse effect being true and correct and the representations and warranties of the other party not so qualified being true and correct in all material respects;

the other party having performed, in all material respects, all obligations required to be performed by it under the merger agreement;

delivery to each party of a certificate executed by the other party s chief executive officer and chief financial officer to the effect that the preceding two conditions have been satisfied;

receipt of an opinion of that party s tax counsel to the effect that the merger will qualify as a tax-free reorganization; and

#### absence of any material adverse effect with respect to the other party. Additional Conditions to the Obligations of Indevus and Merger Sub

The obligations of Indevus and Merger Sub to complete the merger are subject to the satisfaction or waiver of the following additional conditions:

holders of not more than 10% of the outstanding shares of Valera common stock having exercised their dissenters rights under Delaware law and receipt of a certificate from Valera s chief executive officer and chief financial officer certifying this fact; and

absence of any pending suit, action or proceeding by any governmental entity seeking to prohibit or impose any material limitations on Indevus ownership of Valera or the operation of all or a material portion of Indevus or Valera's businesses or assets, or to compel Indevus or Valera or any of their respective subsidiaries to dispose of or hold separate any material portion of the business or assets of Indevus or Valera in any case which is reasonably likely to have a material adverse effect on Indevus (determined after giving effect to the merger) or a material adverse effect on Valera.

#### **Termination of the Merger Agreement**

The merger agreement may be terminated and the merger may be abandoned at any time prior to the closing of the merger, whether before or after receipt of the Valera stockholder approval or Indevus stockholder approval, as applicable, in any of the following ways:

by mutual written consent of Indevus and Valera;

by either Indevus or Valera if:

the merger has not been completed by August 11, 2007, which we refer as the Outside Date; except that a party may not terminate the merger agreement if that party s failure to fulfill any of its obligations under merger agreement is the primary cause of, or resulted in, the merger not being completed by the Outside Date;

Indevus stockholder approval is not obtained at Indevus stockholders meeting or at any adjournment or postponement at which the vote to obtain the approval required for the merger is taken, except that this termination right is not available to Indevus where the failure to obtain Indevus stockholder approval is caused by or related to Indevus material breach of its obligations under the merger agreement; and

Valera stockholder approval is not obtained at Valera's stockholders' meeting or at any adjournment or postponement at which the vote to obtain the approval required for the merger is taken, except that this termination right is not available to Valera where the failure to obtain Valera stockholder approval is caused by or related to Valera's material breach of its obligations under the merger agreement;

any judgment or legal prohibition of any court or other governmental entity that prohibits the completion of the merger becomes final and nonappealable.

by Indevus:

upon a material breach of any representation, warranty, covenant or agreement on the part of Valera such that the conditions to Indevus obligations to complete the merger would not then be satisfied and this breach is incapable of being cured or is not cured by Valera within 20 calendar days after receipt of written notice from Indevus of the breach;

if Valera s board of directors (i) fails to recommend that Valera stockholders adopt the merger agreement, or withdraws or modifies its recommendation in a manner adverse to Indevus, (ii) approves or recommends to its stockholders an alternative transaction or (iii) publicly proposes to take any of these actions;

if Valera s board of directors fails to reconfirm publicly its approval and recommendation of the merger within seven days of Indevus written request for reaffirmation; or

if Valera has (i) materially breached any of its non-solicitation and board recommendation obligations under the merger agreement or (ii) failed to use its reasonable best efforts to solicit proxies in favor of the adoption of the merger agreement

and to obtain the Valera stockholder approval and this failure was a material breach of its obligations to solicit these proxies;

by Valera:

upon a material breach of any representation, warranty, covenant or agreement on the part of Indevus such that the conditions to Valera s obligations to complete the merger would not then be satisfied and this breach is incapable of being cured or is not cured by Indevus within 20 calendar days after receipt of written notice from Valera of the breach;

if Indevus board of directors fails to recommend that Indevus stockholders approve the issuance of Indevus common stock and contingent stock rights in connection with the merger, withdraws or modifies its recommendation in a manner adverse to Valera, or publicly proposes to take any of these actions;

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if Indevus board of directors fails to reconfirm publicly its approval and recommendation of the merger within seven days of Valera s written request for reaffirmation;

if Indevus has (i) materially breached its board recommendation obligations under the merger agreement or (ii) failed to use its reasonable best efforts to solicit proxies in favor of approval of the issuance of Indevus common stock and contingent stock rights in connection with the merger and to obtain the Indevus stockholder approval and the failure was a material breach of its obligations to solicit these proxies; or

if, prior to obtaining Valera stockholder approval of the merger, the board of directors of Valera authorizes Valera to enter into a binding written agreement concerning a Superior Proposal, provided that Valera must have complied with its non-solicitation obligations and at the time of termination must pay a termination fee.

#### **Termination Fees; Reimbursement of Expenses**

If the merger agreement is validly terminated, the merger agreement will become void and of no effect, with no liability on the part of any party to the merger agreement, unless the party is in willful breach of any representation, warranty or covenant contained in the merger agreement. The provisions of the merger agreement relating to the effects of termination; fees and expenses; termination payments; amendment of the merger agreement; the party s representations and warranties relating to brokers; the effect of delivery of certain notices on the representations and warranties, remedies and conditions of the parties; and the general provisions of the merger agreement contained in Article VIII will continue in effect notwithstanding termination of the merger agreement.

Under the circumstances described below, Valera or Indevus, as applicable, would be required to (i) reimburse the other party for the other party s reasonable, out-of-pocket fees and expenses incurred in connection with the merger agreement in an amount not to exceed \$3 million or (ii) pay a termination fee of \$5 million provided that any termination fee payable will be reduced by the amount of any fees and expenses previously reimbursed.

#### (1) Termination due to a Change in Board of Directors Recommendation

A termination fee would be payable by a party if the other party terminates the merger agreement because the party s board of directors (i) withdraws or modifies, or proposes publicly to withdraw or modify, its approval or recommendation of the merger (whether or not in connection with a competing proposal) or (ii) fails to reaffirm publicly it recommendation to its stockholders to vote in favor of the merger within seven days of the receipt by the party of a written request from the other party for reaffirmation.

(2) Termination due to a Superior Proposal

A termination fee would be payable by a Valera if, prior to obtaining Valera stockholder approval of the merger, the board of directors of Valera authorizes Valera to enter into a binding written agreement concerning a Superior Proposal and Valera terminates the merger agreement to pursue the Superior Proposal, provided that Valera must have complied with its non-solicitation obligations described above under No Solicitation by Valera.

(3) Termination due to Failure to Obtain Stockholder Approval, Breach of Merger Agreement or Failure to Close by the Outside Date

Fifty percent of the termination fee would be payable by a party if: (i) that party becomes the subject of a publicly-known takeover proposal (and the takeover proposal is not withdrawn prior to the party s

stockholder meeting) and (ii) the merger agreement is terminated (x) by either party because of the party s failure to obtain stockholder approval of the merger, (y) by the other party because of the party s material breach of its representations, warranties, covenants or agreement contained in the merger agreement or (z) by either party because the merger has not closed by the Outside Date (but only if the party s stockholder meeting has not been held). The other fifty percent of the termination fee would be payable by the party if it enters into a definitive agreement with respect to, or consummates, a takeover proposal within twelve months after the termination of the merger agreement.

Provided that a termination fee is not otherwise payable, reimbursement for fees and expenses would be payable by a party if the other party terminated the merger agreement because of the other party s failure to obtain stockholder approval of the merger or the party s material breach of its representations, warranties, covenants or agreements contained in the merger agreement.

#### Amendments, Extensions and Waivers

The merger agreement may be amended by the parties at any time before or after approval of the merger by Valera and Indevus stockholders. However, after approval by the stockholders of both parties, there may not be, without further approval of Valera stockholders and Indevus stockholders, any amendment of the merger agreement that changes the amount or the form of the consideration to be delivered to Valera stockholders, or any amendment for which applicable law expressly requires further stockholder approval.

At any time prior to the closing of the merger, with certain exceptions, any party may, in an instrument in writing signed by that party:

extend the time for performance of any obligations or other acts of the other party;

waive any inaccuracies of any representations and warranties of the other party contained in the merger agreement; or

waive compliance by the other party with any of the agreements, covenants or conditions contained in the merger agreement.

#### THE VOTING AGREEMENTS

The following summary describes the material terms of the voting agreements entered into by certain Valera stockholders in connection with the merger. The following summary is qualified in its entirety by reference to the complete text of the voting agreements, which are included in this joint proxy statement/prospectus as Annex D-1 and Annex D-2, respectively, and which we incorporate by reference into this joint proxy statement/prospectus. This summary may not contain all of the information about the voting agreements that is important to you. We encourage you to read the voting agreements carefully in their entirety because these documents are the legal documents governing the agreement between Indevus, Merger Sub and each of these Valera stockholders.

Concurrently with the execution and delivery of the merger agreement and as an inducement for Indevus and Merger Sub to enter into the merger agreement, certain affiliated funds of Sanders Morris Harris, Inc., or SMH, and Psilos Group Partners II-S, L.P., or Psilos, entered into voting agreements with Indevus and Merger Sub. As of the record date for the Valera special meeting, SMH and Psilos were the record and/or beneficial owners, respectively, of 5,449,980 and 728,037 shares of Valera common stock. Those shares represent approximately 36.37% and 4.86%, respectively, and approximately 41.23% in the aggregate, of Valera s outstanding shares of common stock as of the record date. James C. Gale, the chairman of Valera s board of directors, is a managing director of SMH. Jeffrey M. Krauss, a member of Valera s board of directors, is affiliated with Psilos.

#### **Voting and Proxies**

Pursuant to and during the terms of the voting agreements, each stockholder party to a voting agreement has agreed to vote, or cause to be voted, all of the Valera common stock owned by the stockholder and all shares of Valera common stock subsequently acquired by the stockholder:

to adopt and approve the merger agreement and each of the other actions contemplated by the merger agreement or the stockholder s voting agreement;

against any action, proposal, transaction or agreement that would result in a breach of any covenant, representation or warranty or any other obligation of Valera contained in the merger agreement; and

against the following actions (other than the merger and the transactions contemplated by the merger agreement):

any other takeover proposal;

any extraordinary corporate transaction, such as a merger, consolidation or other business combination involving Valera;

a sale, lease or transfer of a material amount of assets of Valera or a reorganization, recapitalization, dissolution or liquidation of Valera;

(i) any change in the majority of Valera s board of directors; (ii) any material change in the present capitalization of Valera or any amendment to the Valera organizational documents; (iii) any other material change in the corporate structure or business of Valera; or (iv) any other action which, in the case of each of the matters referred to in clauses (i), (ii) or (iii) above, is intended, or could reasonably be expected, to impede, interfere with, delay, postpone, discourage or adversely affect the contemplated economic benefits to Indevus or Merger Sub of the merger or the transactions contemplated by the merger agreement or the voting agreement or could reasonably be expected to result in any of the conditions to Valera s obligations under the merger agreement not being fulfilled.

The agreement to vote its Valera common stock as described above is subject to certain limitations if Valera s board of directors changes its recommendation with respect to the merger. Under those circumstances, each of SMH and Psilos is required to vote in a manner set forth above

only a number of shares of Valera common stock equal to one half of the outstanding shares of Valera common stock that it owns, with the

remaining half of its Valera common stock required to be voted in a manner that is proportionate to the manner in which all other Valera common stock not beneficially owned by SMH or Psilos is voted.

In addition, each of SMH and Psilos has granted Indevus an irrevocable proxy to vote its shares of Valera common stock in the manner described above.

#### **Prohibited Actions**

Each of SMH and Psilos has also agreed with respect to the shares of Valera common stock subject to the voting agreement that it will not:

offer for sale, sell (including short sales), transfer, tender, pledge, encumber, assign or otherwise dispose of (including by gift), or enter into any contract, option, derivative, hedging or other agreement or understanding to so transfer or otherwise dispose of the shares;

permit to exist any lien of any nature whatsoever with respect to any or all of the shares;

grant any proxy, power-of-attorney or other authorization in or with respect to the shares;

deposit the shares into a voting trust or enter into a voting agreement or arrangement with respect to the shares;

request that Valera register the transfer of any certificate or uncertificated interest in the shares except in accordance with the voting agreement;

exercise any rights of appraisal or rights to dissent from the merger; or

take any other action that would in any way restrict, limit or interfere with the performance of the stockholder s obligations under the voting agreement or the transactions contemplated by the voting agreement or the merger agreement.

#### **Termination of Voting Agreements**

The voting agreements terminate upon the earliest to occur of (i) mutual consent of Indevus, Merger Sub and SMH or Psilos, as applicable, (ii) the termination of the merger agreement in accordance with its terms or (iii) the closing of the merger.

#### THE CONTINGENT STOCK RIGHTS AGREEMENTS

In connection with the closing of the merger, Indevus and a rights agent to be determined will enter into a separate contingent stock rights agreement for each of three Valera products in development Supprelin-LA, the ureteral stent and VP003 (Octreotide implant) substantially in the forms of the contingent stock rights agreements included in this joint proxy statement/prospectus as Annex E-1, Annex E-2, and Annex E-3, respectively, which we incorporate by reference into this joint proxy statement/prospectus. The following summary describes the material provisions of the contingent stock rights agreements. This summary may not contain all of the information about the contingent stock rights agreements that is important to you. We encourage you to read the forms of contingent stock rights agreements governing the contingent stock rights agreements such the rights agent, these documents will be the legal documents governing the contingent stock rights agreements negotiated and entered into with the chosen rights agent to differ from the forms of contingent stock rights agreements included with this joint proxy statement/prospectus in respects that would be material to holders of contingent stock rights, there can be no assurance that any changes will not, in fact, be material to holders.

In addition to the shares of Indevus common stock, for each share of Valera common stock Valera stockholders also will receive three contingent stock rights, which we refer to as CSRs. Each CSR will be subject to the terms and conditions set forth in a separate contingent stock rights agreement, which we refer to as a CSR agreement, to be entered into between Indevus and a rights agent and relates to one of three Valera products in development Supprelin-LA, the ureteral stent and VP003 (Octreotide implant).

#### **No Certificates**

The CSRs will not be evidenced by a certificate or other instrument. A CSR Register will be maintained by the rights agent and will serve as evidence of the registered ownership of CSRs. The CSRs initially will be registered in the names and addresses of, and in the denominations as set forth in, the applicable letter of transmittal accompanying the shares of Valera common stock surrendered by the Valera stockholder in connection with the merger.

#### **CSRs Non-transferable**

The CSRs and any interest in the CSRs may not be sold, assigned, transferred, pledged, encumbered or in any other manner transferred or disposed of, in whole or in part, other than through a permitted transfer and, in the case of a permitted transfer, only in accordance with the provisions of the CSR agreement regarding procedures for transfer and in compliance with applicable United States federal and state securities laws. For purposes of the CSR agreements, a permitted transfer means:

the transfer of any or all of the CSRs on death by will or intestacy;

transfer by instrument to an inter vivos or testamentary trust in which the CSRs are to be passed to beneficiaries upon the death of the trustee;

transfers made pursuant to a court order of a court of competent jurisdiction (such as in connection with divorce, bankruptcy or liquidation);

if the holder is a partnership or limited liability company, a distribution by the transferring partnership or limited liability company to its partners or members, as applicable; or

a transfer made by operation of law (such as a merger). **Convertibility of CSRs** 

Upon the occurrence of the applicable Milestone Date (described below), the CSRs with respect to Supprelin-LA, the ureteral stent and VP003 (Octreotide implant) will become convertible into \$1.00, \$1.00 and

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\$1.50, respectively, worth of Indevus common stock calculated using the average of the per share closing sale prices of Indevus common stock as reported by Nasdaq for the ten trading days ending three trading days prior to the occurrence of the applicable Milestone Date. Cash, without interest, will be paid in lieu of any fractional shares of Indevus common stock a holder would otherwise be entitled to receive upon conversion. In addition, holders of each CSR will be entitled to the amount of any dividends or other distributions, without interest, declared by Indevus on the common stock with a record date after the applicable Milestone Date.

Milestone Date means with respect to:

Supprelin-LA, the date on which both of the following states of affairs exists:

Indevus has received the approval letter from the U.S. Food and Drug Administration, or the FDA, with respect to its New Drug Application for Supprelin-LA, and the FDA approval remains in effect; and

Indevus possesses an inventory of 1,482 commercially saleable units of Supprelin-LA;

the ureteral stent, the date on which Indevus receives the approval letter from the FDA with respect to its Premarket Application or 510k Application for the ureteral stent; and

VP003 (Octreotide implant), the date on which Indevus receives the approval letter from the FDA with respect to its New Drug Application for VP003 (Octreotide implant) for acromegaly.

In order to receive the Indevus common stock issuable upon conversion of the respective CSRs, and any dividend or other distribution on the common stock to which such holder may be entitled, such holder must follow the conversion procedures described below in the section entitled Conversion Procedures.

#### **Conversion Procedures**

Upon the occurrence of the applicable Milestone Date, the respective CSR may be converted by the holder at any time prior to 5:00 p.m., New York City time, on the five year anniversary of the closing of the merger, by following the conversion procedures described below. After that date, all rights in respect of that CSR and under the respective CSR agreement will cease.

Indevus is required to give prompt written notice to the rights agent that the applicable Milestone Date has occurred. Within 5 business days after receiving such notification from Indevus, the rights agent is required to mail by first class mail, postage prepaid, to each holder:

a notice specifying that the Milestone Date has occurred and that the CSR has been converted into the right to receive Indevus common stock pursuant to its terms;

a Letter of Conversion with instructions for completing the Letter of Conversion and delivering it to the rights agent in exchange for a certificate representing shares of Indevus Common Stock and for cash in lieu of a fractional share and, if applicable, cash payable pursuant to dividends or other distributions on the common stock to which the holder may be entitled.

In addition, the Company will post an appropriate notice of the Milestone Date on its Internet website and issue a press release announcing the occurrence of the Milestone Date.

Upon delivery by the holder of a properly completed Letter of Conversion to the rights agent, the rights agent will deliver a written order to Indevus, which we refer to as the issuance order, specifying the issuance and payment (without interest) to the holder of:

a certificate representing that number of whole shares of Indevus common stock into which the CSRs of such holder have been converted pursuant to the provisions of the applicable CSR agreement; and

a check in the amount of any cash due in lieu of a fractional share of Indevus common stock and pursuant to any dividend or other distribution on the common stock to which the holder may be entitled.

Upon delivery of the issuance order by the rights agent to Indevus, Indevus will issue and cause to be delivered to the holder with all reasonable dispatch a certificate for that number of shares of Indevus common stock and a check for any amount of cash due to the holder.

#### Limitation on Aggregate Amount of Indevus Common Stock Issuable

The aggregate number of shares of Indevus common stock issuable upon conversion of the three CSRs pursuant to the terms of the CSR agreements may not exceed the number of shares of Indevus common stock that is issued as part of the merger consideration provided at completion of the merger. The exchange ratio with respect to the conversion of the respective CSRs will be recalculated, as necessary, at the time of conversion of the CSRs so that it results in the maximum number of shares of Indevus common stock becoming issuable without violating this provision.

#### **Termination of CSRs**

If the Milestone Date does not occur within three years of completing the merger in the case of Supprelin-LA or within five years of completing the merger in the case of the ureteral stent and VP003 (Octreotide implant), the respective CSRs will terminate and no shares of Indevus common stock will be issued in connection with those CSRs.

#### Adjustment of CSRs

If, during the period of time used to determine the Indevus stock price for purposes of determining the number of shares issuable upon conversion of a particular CSR, there is a change in the number of issued and outstanding shares of Indevus common stock as the result of a reclassification, subdivision, recapitalization, stock split (including reverse stock split) or stock dividend, then the number of shares of Indevus common stock issuable upon the conversion of the CSR in effect immediately prior to such action will be proportionately adjusted, as necessary, so that the holder of any CSR thereafter converted may receive the aggregate number and kind of shares of capital stock of Indevus that the holder would have owned immediately following that action if the CSR had been converted immediately prior to that action.

In the event of any of the following actions (which are collectively referred to as Reorganizations ):

any capital reorganization, other than in the cases referred to in the paragraph above and other than any capital reorganization that does not result in any reclassification of the outstanding shares of Indevus common stock into shares of other stock or other securities or property;

the consolidation or merger of Indevus with or into another corporation (other than a merger or consolidation in which Indevus is the continuing corporation and which does not result in any reclassification of the outstanding shares of Indevus common stock into shares of other stock or other securities or property); or

#### the sale of all or substantially all of the assets of Indevus;

upon conversion of a CSR in accordance with the terms of the applicable CSR agreement, the holder shall be entitled (in lieu of the number of shares of Indevus common stock that was previously deliverable) to the number of shares of stock or other securities, property or cash to which a holder of the number of shares of Indevus common stock that would otherwise have been deliverable upon the conversion of the CSR would have been entitled upon the Reorganization if the applicable Milestone Date had occurred and the CSR had been converted in full immediately prior to the Reorganization. In case of any Reorganization, appropriate adjustment, as determined in good faith by Indevus board of directors, whose determination will be described in a duly adopted resolution certified by Indevus secretary or assistant secretary, will be made in the application of the provisions of the applicable CSR agreement with respect to the rights and interests of holders so that the CSR agreement provisions will thereafter be applicable, as nearly as possible, in relation to any shares or other securities, property or cash thereafter deliverable upon conversion of the CSRs.

Indevus will not effect any Reorganization unless prior to or simultaneously with the consummation of a Reorganization the successor corporation (if it is not Indevus) resulting from the Reorganization or the corporation or other entity purchasing the assets expressly assumes, by a supplemental CSR agreement or other acknowledgment executed and delivered to the rights agent, the obligation to deliver to the rights agent and to cause the rights agent to deliver to each CSR holder such shares of stock, securities or assets as that holder may be entitled to in accordance with the terms the applicable CSR agreement upon the occurrence of the applicable Milestone Date, and the due and punctual performance and observance of each and every covenant, condition, obligation and liability under the respective CSR agreement to be performed and observed by Indevus.

#### **Rights of CSR Holder**

The rights of a holder are limited to those expressed in the applicable CSR agreement. CSRs will not entitle the holders thereof, by virtue of their ownership of CSRs, to any of the rights of an Indevus stockholder.

#### Amendment of a CSR Agreement Without the Consent of CSR Holders

Without the consent of the holders, Indevus and the rights agent, at any time and from time to time, may enter into one or more amendments to the CSR agreements, for any of the following purposes:

to evidence the succession of another person to Indevus and the assumption by any successor of the covenants of Indevus in the respective CSR agreement;

to evidence the succession of another person as a successor rights agent and the assumption by any successor of the covenants and obligations of the rights agent;

to add to the covenants of Indevus any further covenants, restrictions, conditions or provisions as Indevus considers to be for the protection of CSR holders; *provided* that in each case, the provisions do not adversely affect the rights of CSR holders; or

to cure any ambiguity, to correct or supplement any provision in the respective CSR agreement that may be defective or inconsistent with any other provision, or to make any other provisions with respect to matters or questions arising under the respective CSR agreement; *provided* that in each case, the provisions do not adversely affect the rights of CSR holders.

# Amendment of a CSR Agreement With the Consent of CSR Holders

With the written consent of holders of not less than a majority of the respective CSRs then outstanding, Indevus may enter into one or more amendments to a respective CSR agreement for the purpose of adding, eliminating or changing any provision of the CSR agreement, if the addition, elimination or change is in any way adverse to the rights of CSR holders.

The consent of each holder affected is required for any amendment to a CSR agreement pursuant to which the number of shares of Indevus common stock issuable upon conversion of the respective CSRs would be decreased (not including adjustments contemplated under the respective CSR agreement).

#### **Product Development Efforts**

After the completion of the merger, Indevus will use commercially reasonable efforts to develop, in the ordinary course, Supprelin-LA, the ureteral stent and VP003 (Octreotide implant); *provided*, that, with respect to Supprelin, Indevus obligations will terminate on the third anniversary of the closing of the merger, and with respect to the ureteral stent and Octreotide, Indevus obligations will terminate on the fifth anniversary of the closing of the merger. For purposes of the CSR agreements, commercially reasonable efforts means efforts and resources normally used by Indevus for a product owned by it or to which it has exclusive rights, which is of similar market potential at a similar stage in its development or product life, taking into account issues of safety

and efficacy, product profile, competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory and reimbursement structure involved, the profitability of the applicable products, and other relevant factors. Failure to obtain FDA approval, either at all or on or before a certain date, will not be deemed a breach by Indevus of this provision of the CSR agreements.

#### **Termination of CSR Agreement**

The respective CSR agreements will terminate at 5:00 p.m., New York City time, on the fifth anniversary of completing the merger, or, in the case of the CSR agreement relating to Supprelin-LA, on the third anniversary of completing the merger if the Milestone Date with respect to Supprelin-LA does not occur prior to that date. The respective CSR agreements will terminate on any earlier date if all respective CSRs have been converted pursuant to the agreement.

## INFORMATION ABOUT INDEVUS

## Business

Indevus is a specialty pharmaceutical company engaged in the acquisition, development and commercialization of products to treat conditions in urology and endocrinology. Indevus currently markets two products through its approximately 80-person specialty sales force and it has six products in development. Indevus marketed products include SANCTURA for overactive bladder, which it co-promotes with its partner Esprit Pharma, Inc., which we refer to in this joint proxy statement/prospectus as Esprit, and DELATESTRYL (testosterone enanthate) for the treatment of male hypogonadism.

Indevus core urology and endocrinology portfolio contains four compounds in development in addition to its marketed products SANCTURA and DELATESTRYL. Its most advanced compound is SANCTURA XR, the once-daily formulation of SANCTURA. In October 2006, Indevus submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, seeking approval to market SANCTURA XR. NEBIDO, for male hypogonadism, is currently in a fully-enrolled, Phase III pharmacokinetic study and Indevus expects to submit an NDA for NEBIDO in mid-2007. PRO 2000, a topical microbicide for the prevention of infection by HIV and other sexually-transmitted diseases, is in two ongoing Phase III trials. IP 751 is for pain and inflammatory disorders, including interstitial cystitis.

In addition to its core urology and endocrinology portfolio, Indevus is preparing to begin a Phase III development program for pagoclone, a GABA-A (gamma amino butyric acid) receptor modulator which it is developing for the treatment of persistent developmental stuttering. Indevus product portfolio also contains aminocandin, an echinocandin for systemic fungal infections for which Indevus recently licensed worldwide rights to Novexel S.A, a spin-out company from sanofi-aventis. Indevus also is receiving royalties under a patent it licensed to Eli Lilly & Company based on net sales of Sarafem<sup>®</sup> in the United States. Sarafem is prescribed to treat certain conditions and symptoms associated with pre-menstrual dysphoric disorder.

In December 2006, Indevus entered into a co-promotion arrangement with Valera and in January 2007, pursuant to the co-promotion arrangement, Indevus and Valera began to jointly market Vantas with an aggregate sales force of approximately 105 individuals that are currently calling on urologists in the United States that account for the majority of LHRH agonist product sales.

#### Strategy

Indevus goal is to become a leading specialty pharmaceutical company focused on urology and endocrinology. The key elements of the strategy that Indevus employs in its efforts to achieve its goal include:

(1) Identifying and acquiring products or product candidates that have differentiating features and defined specialty markets within Indevus core focus area.

(2) Adding value to acquired development stage compounds through research, pre-clinical development, clinical testing and regulatory activities.

(3) Commercializing products with our specialty sales force or in collaboration with corporate partners in order to help ensure broader penetration of target markets.

#### Core Focus Area Urology and Endocrinology

In urology and endocrinology, Indevus believes it has developed strong capabilities in product development based on its research and development organization and in sales and marketing based on its approximately 80-person specialty sales force.

Through Indevus business development efforts and its research and development capabilities, Indevus has a robust late-stage product pipeline. Indevus believes its capabilities will enable it to continue to successfully

acquire, develop and commercialize products and product candidates and achieve its strategic goal of becoming a leading specialty pharmaceutical company in its core focus area.

The following table outlines the products in its core focus area:

Product Name SANCTURA	Indication/Use Overactive bladder	<b>Status</b> Marketed	<b>Commercial</b> <b>Rights</b> U.S. <sup>1</sup>
SANCTURA XR	Overactive bladder	NDA <sup>2</sup> filed	Worldwide <sup>3</sup>
DELATESTRYL	Hypogonadism	Marketed	U.S.
NEBIDO	Hypogonadism	Phase III	U.S.
PRO 2000	HIV and STD prevention	Phase III	Worldwide
IP 751	Interstitial cystitis/pain	Phase I	Worldwide

<sup>1</sup> Licensed to Esprit.

<sup>2</sup> NDA refers to a New Drug Application.

<sup>3</sup> Licensed to Esprit in the U.S.; certain territories outside the U.S. licensed to Madaus GmbH.

#### **Other Products**

In addition to the products and product candidates in its core focus area, it has products and product candidates that address certain other specialty medical areas.

The following table summarizes the status of its other products:

<b>Product Name</b> Sarafem	Indication/Use Premenstrual Dysphoric Disorder	<b>Status</b> Marketed	<b>Commercial Rights</b> Worldwide <sup>1</sup>
Pagoclone	Stuttering	Phase III	Worldwide
Aminocandin	Systemic fungal infections	Phase I	Worldwide <sup>2</sup>

<sup>1</sup> Licensed to Eli Lilly & Company

<sup>2</sup> Know-how licensed to Novexel S.A.

Indevus Pharmaceuticals, Inc. is a Delaware corporation. Its principal office is located at 33 Hayden Avenue, Lexington, Massachusetts 02421-7971, and its main telephone number is (781) 861-8444. Reports, proxy statements and other information concerning Indevus may be accessed and reviewed through its website at www.indevus.com.

Indevus registered trademark SANCTURA is assigned in the U.S. to Esprit Pharma Holding Company (subject to our co-exclusive right to use it) and NEBIDO is a registered trademark of Schering AG, Germany that Indevus exclusively licenses in the United States. DELATESTRYL is Indevus registered trademark for its DELATESTRYL product. Indevus has pending trademark applications for SANCTURA XR. Other trademarks, trade names and service marks appearing in this registration statement are the property of their respective owners.

#### **INFORMATION ABOUT VALERA**

#### Overview

Valera Pharmaceuticals is a specialty pharmaceutical company concentrating on the development, acquisition and commercialization of products for the treatment of urological and endocrine conditions, diseases and disorders, including products that utilize Valera's proprietary drug delivery technology. Valera's first product, Vantas, was approved by the U.S. Food and Drug Administration, or FDA, in October 2004. Vantas is a 12-month implant indicated for the palliative treatment of advanced prostate cancer. Vantas slows prostate tumor growth by delivering histrelin, a luteinizing hormone-releasing hormone agonist, or LHRH agonist. Valera began marketing Vantas in November 2004 utilizing its sales force. In December 2006, Valera entered into a co-promotion agreement with Indevus and in January 2007, pursuant to the co-promotion arrangement, Valera and Indevus began to jointly promote Vantas with Indevus with an aggregate sales force of approximately 105 individuals that are currently calling on urologists in the United States that account for the majority of LHRH agonist product sales. In addition to Vantas, Valera is developing a pipeline of product candidates for indications that include central precocious puberty, acromegaly, bladder cancer, opioid addiction, interstitial cystitis, nocturnal enuresis and bladder cancer.

Total U.S sales of LHRH agonist products for the palliative treatment of prostate cancer were approximately \$850 million in 2006 based on Valera's estimates and IMS Health Incorporated data, with the leading products being three- and four-month injection formulations. Valera's believes that total U.S. sales of LHRH agonist products declined by approximately 5% in 2006, primarily as a result of lower prices due to changes in Medicare reimbursement rates. Valera believes that Vantas has a competitive advantage over other products because it delivers an even, controlled dose of LHRH agonist over a 12-month period, and is the only product indicated for the palliative treatment of advanced prostate cancer that delivers histrelin, the most potent LHRH agonist available on the market.

Vantas is a hydrogel implant based on Valera s patented Hydron Technology, which is a drug delivery system that allows Valera to control the amount and timing of the release of drugs into the body for up to 12 months. Several of Valera s product candidates utilize its Hydron Technology delivery system. The hydrogel implant is a soft and flexible implant containing no moving parts. Valera intends to leverage its specialized sales force to market certain of its product candidates, if approved, since the indications of these product candidates are treated by many of the same physicians Valera is calling on for Vantas.

Valera is a Delaware corporation. Its principal office is located at 7 Clarke Drive, Cranbury, NJ 08512, and its main telephone number is (609) 235-3000. Reports and other information concerning Valera may be accessed and reviewed through its website at www.valerapharma.com.

#### Valera s Competitive Strengths

Valera believes that its key competitive strengths that allow it to compete effectively in the urology and endocrinology markets include:

*Technology*. Valera believes that Hydron Technology offers significant advantages over existing drug delivery systems. Implants using Hydron Technology can be adapted to deliver many kinds of drugs over an extended period of time. In addition, Valera s implants are soft and flexible, enhancing patient comfort. Further, because Valera owns the manufacturing know-how to develop products utilizing Hydron Technology, Valera is able to control and maximize the potential commercial uses of this technology.

*Development Capability.* As demonstrated by Vantas, Valera has succeeded in developing a product, successfully taking it through the regulatory process to market in the United States in less than a year from the submission of a new drug application without utilizing an accelerated approval process. However, Valera may not be able to obtain FDA approval for its product candidates as quickly as it did for Vantas. Valera expects to continue to utilize this capability to efficiently develop future products.

*Manufacturing Ability*. Valera manufactures Vantas and Valera s product candidates utilizing Hydron Technology using a patented and proprietary process. In addition, Valera has developed proprietary equipment and scalable manufacturing methods to achieve cost-effective commercial production. Further, because Valera controls the manufacture of Vantas and Valera s product candidates that use Hydron Technology, Valera can ensure high quality and fully realize any manufacturing cost efficiencies.

*Sales and Marketing.* Valera and its co-marketing partner, Indevus, are currently calling on urologists that account for the majority of LHRH agonist product sales in the United States. By adjusting Valera's current sales force structure slightly, Valera will be able to call on physicians in additional specialty areas, such as pediatric endocrinology. These therapeutic areas are attractive because they can be effectively targeted with a small, focused sales force. Valera also believes that the direct physician distribution channel of Vantas may present a barrier to the future entry of competition from generic products because generic drug companies do not typically have field sales forces. Outside the United States, Valera has partnered with companies with a local presence and proven distribution channels in the urology market for distribution of Vantas.

#### **Product Development**

The following table summarizes certain information regarding Vantas and Valera s product candidates:

<b>Product</b> Vantas	Indication Prostate Cancer	<b>Therapeutic Area</b> Urology	<b>Delivery Method</b> Implant	Status United States Commercial Sales; Approved in Denmark and Canada
Supprelin <sup>®</sup> -LA	Central Precocious Puberty (early onset of puberty)	Endocrinology	Implant	New Drug Application Filed
VP003 (Octreotide)	Acromegaly (giantism)	Endocrinology	Implant	Phases I/II
VP004 (Naltrexone)	Addiction Disorders	Central Nervous System	Implant	Phase I/II
VP005 (Anti-inflammatory)	Interstitial Cystitis (bladder inflammation)	Urology	Bladder Instillation	Pre-clinical
VP006 (Peptide)	Nocturnal Enuresis (bed wetting)	Urology	Oral Tablet	Phase I
Valstar <sup>®</sup> (Valrubicin)	Bladder Cancer	Urology	Bladder Instillation	New Drug Application Approved
Endoureteral Stent Vantas	Maintenance of Ureteral Patency	Urology	Insertion	Pivotal Animal Study

Vantas is a soft and flexible 12-month hydrogel implant based on Valera s patented Hydron Technology indicated for the palliative treatment of advanced prostate cancer that delivers histrelin, a luteinizing hormone-releasing hormone agonist, or LHRH agonist, over a 12-month period for the palliative treatment of advanced

prostate cancer. Valera began marketing Vantas in the United States in November 2004 utilizing its own sales force. In December 2006, Valera entered into a co-promotion agreement with Indevus and in January 2007, pursuant to the co-promotion agreement, Valera began to jointly promote Vantas with Indevus with an aggregate sales force of approximately 105 individuals that are currently calling on urologists in the United States that account for the majority of LHRH agonist product sales. In November 2005, Valera announced that it received approval to market Vantas in Denmark and in July 2006, Valera submitted an application for regulatory approval in Germany, Ireland, Italy, Spain and the United Kingdom. In July 2006, Valera announced a partnership with Spepharm to market Vantas in Denmark and throughout Europe. Valera has completed the primary stage of the Mutual Recognition Procedure (MRP) process which concluded with a non-approvable status and referral to the Co-ordination Group for Mutual Recognition and Decentralized Procedure-Human, CMD(h). The CMD(h) arbitration failed to reach a consensus on approval and the procedure has been further referred to the Committee for Medicinal Products for Human Use (CHMP) at the European Agency for the Evaluation of Medicinal Products (EMEA). This final CHMP arbitration process will include all twenty-seven countries in the European Union where a majority rule will apply. In March 2006, Valera announced that Paladin Labs, Valera s marketing partner in Canada, received approval from Health Canada to market Vantas in Canada. Subsequently, Paladin Labs submitted an application for reimbursement to the Canadian Common Drug Review (CDR) and the Conseil du Médicament du Québec and this documentation is under review. As of December 31, 2006, in conjunction with BioPro Pharmaceutical Inc., Valera s marketing partner for most countries in Asia, Vantas was submitted for regulatory approval in Thailand, Singapore, Malaysia, Taiwan, Korea Hong Kong and China.

The current standard of care for the palliative treatment of prostate cancer is LHRH agonist therapy. An agonist is a chemical substance capable of activating a receptor to induce a full or partial pharmacological response. LHRH agonist therapies for advanced prostate cancer are designed to suppress the production of testosterone because testosterone promotes and accelerates the growth of tumors associated with prostate cancer. Histrelin, a powerful inhibitor of testosterone production, is the most potent LHRH agonist available.

The most common dosage forms for the administration of LHRH agonists for the palliative treatment of prostate cancer involve three- and four-month injection formulations such as Lupron and Eligard, which deliver leuprolide, Trelstar, which delivers triptorelin, and Zoladex, a biodegradable rod, which delivers goserelin. Another product is Viadur, a rigid metal implant that releases leuprolide over a 12-month period. Valera believes that Vantas is a more comfortable and convenient alternative to competing products because it eliminates the requirement of multiple physician visits and repeated injections and is smaller, softer and more flexible than other implants. Implantation, however, may be less well-received by some patients than injection therapy. In addition, in Valera's Phase III clinical trial for Vantas, 100% of the evaluable patients achieved chemical castration at week four and testosterone suppression was maintained throughout the 52-week study period for 99% of the patients. Based on these data, Valera believes Vantas is a highly effective product for the palliative treatment of advanced prostate cancer. During the Phase III clinical trial, side effects included hot flashes, fatigue and implant site reactions, such as swelling and redness.

Prostate cancer is the most common cancer for men other than skin cancers and the second leading cause of cancer death in men. According to the American Cancer Society, every year approximately 220,000 men are diagnosed with prostate cancer and approximately 27,000 die from this disease. The National Cancer Institute s SEER Program and the National Oncology Database each project that this patient group will grow at an annual rate of 2% to 3% per year through 2008 and beyond.

Along with its co-marketing partner, Indevus, Valera is currently selling and marketing Vantas to the urologists that account for the majority of LHRH agonist product sales in the United States. Valera s product specialists utilize various promotional materials when making clinical presentations, including instructional videos on proper implantation technique. In remote areas where Valera s product specialists cannot make personal visits, Valera conducts direct mail programs to selected physicians. Additionally, Valera supports its sales efforts by employing a wide range of marketing programs to promote Vantas, including journal advertising, industry publications, medical educational conferences and Internet initiatives.

## Supprelin-LA

Supprelin-LA is an implant utilizing Valera's Hydron Technology to deliver histrelin over a 12-month period for the treatment of central precocious puberty, or CPP. The incidence of this condition is estimated to be between one in 5,000 to 10,000 children. This yields a potential population of up to approximately 12,000 children in the United States with this condition who are treatable. CPP is the early onset of puberty in young children, resulting in the development of secondary sexual characteristics and short stature, if left untreated. The development of these secondary sexual characteristics is due to an increase in the secretion of sex hormones, the cause of which is unknown. The standard of care of CPP involves the use of LHRH agonists to suppress the secretion of sex hormones in order to delay the onset of puberty.

One therapy currently marketed to treat CPP is Lupron Depot-PED, which is manufactured and marketed by TAP Pharmaceutical Products, Inc. According to IMS Health market data, sales of Lupron Depot-PED generated revenues of approximately \$80 million in the United States in 2006. The average monthly cost of Lupron Depot-PED is in excess of \$1,000 per month. CPP treatment using Lupron Depot-PED consists of intramuscular injections of leuprolide every four weeks to hormonally suppress these children. Valera s research indicates that, in many cases, hormonal suppression may not be achieved by a four-week injection schedule, and leuprolide needs to be administered more frequently. Supprelin-LA delivers histrelin, which has ten times the relative potency of leuprolide, and which was previously approved for this condition as a daily injection for children. Supprelin-LA is formulated to release a higher daily dose of histrelin than Vantas because children with CPP need higher doses of LHRH agonist to achieve hormonal suppression. If approved, Supprelin-LA would provide hormonal suppression over a 12-month period. Valera believes Supprelin-LA would have a competitive advantage over Lupron Depot-PED because it eliminates the monthly injections given to these children with a once yearly implant and offers increased convenience and reduced costs by eliminating the need for monthly physician visits. Depending on the age of diagnosis, typical therapy may last three to five years.

In a survey conducted by D2 Market Research on Valera s behalf at the 2004 Pediatric Academic Society conference, over 50% of the pediatric endocrinologists who completed a self-administered questionnaire indicated they would be likely to use a one-year implant like Supprelin-LA. There are approximately 700 pediatric endocrinologists in the United States, and most of them are located in the same major metropolitan areas as the urologists Valera is currently calling on for Vantas. Valera intends to market Supprelin-LA, if approved, by primarily leveraging its existing sales force.

In June 2006, Valera submitted a New Drug Application (NDA) to the FDA for Supprelin-LA. The Phase III study of Supprelin-LA is the basis of the NDA submission. The study was a multi-center, open-label Phase III study which involved 36 patients ranging in age from four to eleven years. Sixteen children had received GnRH therapy prior to enrollment while the remaining twenty were naïve to treatment. The subcutaneous implant was inserted into the inner aspect of the upper arm. The primary endpoints, which were hormonal suppression below pubertal levels and continued suppression upon challenge with gonadotropin-releasing hormone, were met. All patients were analyzed for efficacy and safety. In September 2006, Valera received notice from the FDA, that they had accepted Valera s submission of its NDA for Supprelin-LA and accordingly, under the Prescription Drug User Fee Act (PDUFA) guidelines, the FDA is expected to complete its review and act upon this NDA submission by the PDUFA date of May 3, 2007. Valera also announced in September 2006, its Supprelin-LA manufacturing facilities in Cranbury, New Jersey successfully passed a recent FDA pre-approval inspection. Pursuant to Valera s co-promotion agreement with Indevus, Valera has the option to elect to enter into negotiations with Indevus to grant Indevus a co-exclusive right to co-promote Supprelin-LA.

#### VP003 (Octreotide)

VP003 is an implant utilizing Hydron Technology to deliver octreotide over a six-month period for the treatment of acromegaly, or giantism. Valera believes there are approximately 1,000 new acromegalic patients per year and 16,000 total patients in the United States. Acromegaly is a chronic hormonal disorder that occurs

when a pituitary tumor produces excess growth hormone, or GH. It most commonly affects middle-aged adults, and if untreated, causes enlargement of certain bones, cartilage, muscles, organs and other tissue, leading to serious illness and potential premature death.

Octreotide is a treatment used to substantially reduce GH levels and insulin-like growth factor levels, or IGF-1 levels, in patients with acromegaly. Octreotide is also approved to treat the symptoms associated with metastatic carcinoid tumors and vasoactive intestinal peptide secreting adenomas, which are gastrointestinal tumors. Octreotide is currently being marketed by Novartis as Sandostatin injections in several strengths in both daily and monthly formulations.

Valera estimates the U.S acromegalic market to be approximately \$200 million annually, consisting mostly of monthly injections of octreotide. Valera believes there is a market for a longer- acting octreotide formulation such as VP003 in order to reduce the number of physician visits for injections of octreotide. In addition, since there are a limited number of endocrinologists dispensing octreotide and patients are dispersed throughout the country, Valera believes patient compliance would also be significantly improved by longer-acting treatment with VP003.

Research conducted by Verispan Market Research on Valera s behalf shows that a longer-acting octreotide product would be favorably received in the endocrinology market. The endocrinologists interviewed by Verispan cited the poor compliance of acromegalics who are required to visit a doctor every month to get injections for a disease in which patients rarely notice the changes being caused by the condition. Another reason cited for poor compliance was the long distances many patients have to travel for treatment because of the limited number of physicians willing to administer the monthly formulation of Sandostatin due to the complexity of the technique involved.

There are approximately 4,400 endocrinologists practicing in the United States, and most of them are located in the same metropolitan areas where Valera is marketing Vantas to urologists. Valera intends to market VP003 by creating an endocrine sales force or by partnering with a company that has an existing endocrine sales force.

In 2004, Valera initiated and completed a Phase I/II pharmacokinetic clinical trial with eleven acromegalic patients to evaluate the release characteristics of VP003 and examine safety and efficacy parameters. The endpoints achieved in this clinical trial were the reductions in GH and IGF-1 levels in the blood in these patients. During the Phase I/II clinical trial, side effects included diarrhea, low blood sugar and implant site reactions. In August 2006, the FDA requested an additional Phase I/II pharmacokinetic (PK) study for the Octreotide implant. In September 2006, Valera submitted an Investigational New Drug Application (IND) with the FDA for the Octreotide implant. The application contained Valera s proposed six-month Phase I/II PK study in thirty patients. In January 2007, Valera commenced the study and data is expected to be provided to the FDA for review in June 2007. Valera anticipates commencing a Phase III study in the second half of 2007.

#### VP004 (Naltrexone)

VP004 is an implant utilizing Hydron Technology to deliver naltrexone for the treatment of opioid addiction over a three to six-month period. The National Institute on Drug Abuse estimates that there are approximately one million heroin addicts in the United States of which only 25% seek treatment. Naltrexone is an opiate antagonist currently approved as an oral daily formulation in the United States for the treatment of opiate dependence. Naltrexone competitively binds at the opiate receptor sites in the brain, thereby blocking the euphoric effects of opiates such as heroin.

Although naltrexone is effective, the addict population is typically non-compliant. Valera believes that this creates an attractive opportunity for VP004 because it provides controlled release of naltrexone over a six-month period. There are over 200 registered addiction medicine specialists practicing in the United States. Further, a

significant number of primary care providers treat opioid addicts. In addition to opioid addiction, naltrexone is also currently approved in the United States for the treatment of alcoholism.

In May 2006, Valera submitted an Investigational New Drug Application (IND) for VP004 to the FDA and that filing has been accepted by the agency. In November 2006, Valera finalized all administrative arrangements with Johns Hopkins and commenced clinical studies for VP004. The three month Phase I/II study involves an open label study of the naltrexone implant in approximately a dozen healthy volunteers with a history of opioid abuse. A primary objective of the study is to investigate several dosing regimens for the extent of opiate blockade following morphine challenges. The lead investigator is the pioneering addiction researcher and renowned authority on naltrexone, Donald Jasinski, M.D., Professor of Medicine, Chief Center for Chemical Dependence, Johns Hopkins Bayview Medical Center. The data related to the study is expected to be provided to the FDA for review in the third quarter of 2007. Valera expects to commence a Phase III clinical trial in the first half of 2008.

#### VP005 (Anti-inflammatory)

VP005 is a proprietary polymer solution instillation for the treatment of symptoms associated with interstitial cystitis, a chronic inflammatory condition of the bladder. Interstitial cystitis, or IC, affects approximately one million people in the United States. IC is characterized by frequent urination and pain above the public region. The cause of IC is unknown but is believed to involve inflammation of the bladder.

Valera believes that IC is a disease that has been poorly served by the pharmaceutical industry. Elmiron is the only product currently approved for the relief of bladder pain or discomfort associated with IC. Elmiron is marketed by Bayer HealthCare LLC and is an oral formulation containing 100 milligrams of pentosan polysulfate sodium, a semi-synthetic molecule that is taken three times a day. According to IMS Health market data, sales of Elmiron generated revenues in excess of \$100 million in the United States in 2004. Valera s discussions with urologists indicate that Elmiron is only occasionally effective and that many patients require instillation therapy, a more invasive form of treatment utilizing a catheter to fill up the bladder with various solutions. Instillation therapy has been shown to abate the symptoms of IC in some patients. VP005 is an instillation therapy that forms a temporary coating on the internal lining of the bladder and facilitates the slow, controlled release of the drug in VP005 into the bladder. Valera intends to license the drug delivery technology used in VP005 and intends to apply for patent protection for this application of that technology.

VP005 has been successful in animal models in treating what Valera believes to be the major contributing factor in producing the painful symptoms of IC. Valera has drafted a Phase I/II protocol to evaluate VP005 in humans. In March 2005, Valera met with a panel of IC experts from the United States to help refine the protocol. Valera is currently evaluating the development and commercialization strategy for VP005.

#### VP006 (rapid dissolve desmopressin)

VP006 is a proprietary modified release oral formulation of desmopressin for the treatment of nocturnal enuresis, commonly referred to as bed-wetting. Nocturnal enuresis affects approximately five to seven million children in the United States.

Valera believes that nocturnal enuresis has been poorly served by the pharmaceutical industry. DDAVP, Tofranil and several generics are the products currently approved for the management of nocturnal enuresis. The most common pharmaceutical treatment is DDAVP, which is manufactured and marketed by Sanofi-Aventis.

According to IMS, sales of DDAVP for 2004 were approximately \$220 million. It is available as an oral tablet or a nasal spray containing 0.1-0.2 milligrams of desmopressin acetate, an antidiuretic hormone affecting renal water conservation. Valera believes that the rapidly dissolving formulation of desmopressin would be preferred by children and their parents because young children can have difficulty swallowing solid tablets.

VP006 has been evaluated in bio-availability studies and, while not bioequivalent to the reference drug product, VP006 has shown a similar pharmacodynamic response. Valera is presently exploring the regulatory pathway for the approval of VP006 as well as evaluating the commercialization strategy for this product.

## Valstar<sup>®</sup> (Valrubicin)

In March 2006, Valera completed the acquisition of certain assets from Anthra Pharmaceuticals, Inc. associated with its valrubicin business in the United States and Canada for the purchase price of \$600,000 plus future royalties of up to 13.5% of net sales depending upon the product s formulation, indication and market share plus certain milestone payments based upon achieving certain sales levels. The valrubicin product Valera acquired, formerly marketed in the United States under the trademark Valstar, is a bladder instillation approved to treat bladder cancer that is no longer responsive to conventional treatment such as surgery and/or topical drug application. This product was previously administered and billed as an office procedure, and predominantly covered under Medicare reimbursement. The product is not covered by any patents and its orphan drug status has expired.

According to the National Institutes of Health data, bladder cancer has a prevalence of approximately 500,000 patients in the United States. Market research conducted by Verispan on Valera's behalf and performed at the May 2002 American Urology Association meeting found that approximately 31% of bladder cancer patients are treated with BCG (Bacillus Calmette-Guerin), the most common form of topical treatment. The research further shows that about 17% of the BCG patients become unresponsive, or refractory, to treatment each year and must now either have a cystectomy, the medical term for bladder removal, or stand the chance of disease progression. Urologists surveyed in the study further stated that 69% of these refractory patients go on to have their bladder removed, resulting in a patient population of approximately 8,200 with this type of cancer who could be candidates for valrubicin.

Anthra's product was withdrawn from the market in 2002 due to a manufacturing problem and a lack of resources to address the problem. Valera believes that it has identified the cause of the manufacturing problem and that it will be able to correct the problem. In January 2006, the FDA agreed to Valera's plan to reintroduce the product in the United States. Valera has engaged a third party manufacturer to produce the finished version of Valstar. This manufacturer produced a pilot batch of Valstar, for confirmation of product stability, and in the second quarter of 2007 will initiate validation batches for eventual release and sale. Valera expects to launch the product in the second or third quarter of 2007 depending on the regulatory approval to re-launch the product in the United States.

# Endoureteral Stent

On November 8, 2006, Valera announced that it completed proof-of-concept studies on a flexible, biodegradable polymer-based ureteral stent. Ureteral stents are plastic tubes inserted into the ureter to allow urine to drain from the kidney to the bladder when the flow of urine may be obstructed due to a number of conditions, including kidney stones and inflammation. Current available ureteral stents require physician intervention for removal from the body. A biodegradable ureteral stent could be naturally voided by the body, a potentially important advantage over existing stents. In February 2007, Valera announced that it had initiated a porcine model study to establish safety and effectiveness necessary to support the submission of a 510k device application for the polymer-based flexible biodegradable ureteral stent. This study will involve 30 pigs with a primary end point being the dissolution and natural excretion of the stent within several weeks. Depending on the outcome of the porcine model study, Valera believes the 510k submission could occur by the end of 2007.

In connection with the Revised Research and Development Proposal dated April 27, 2005, between Valera and Poly-Med, Inc. and the Advanced Development and Pilot Production Outline issued by Valera and Poly-Med on March 24, 2006 and revised on April 10, 2006, relating to the development of a biodegradable endoureteral stent, on December 4, 2006, Valera entered into a Letter Agreement with Poly-Med, pursuant to which Valera

agreed to engage in exclusive negotiations to enter into an agreement (the License and Supply Agreement ) providing Valera with an exclusive license to use and sell the endoureteral stent in exchange for certain royalty payments. The License and Supply Agreement will also set forth the terms under which Poly-Med will manufacture and supply Valera with the endoureteral stent. The exclusivity period contemplated by the Letter Agreement expires June 30, 2007.

## **Research and Development Expenditures**

Research and development expense for the years ended December 31, 2006, 2005 and 2004 was \$7.6 million, \$5.9 million and \$6.4 million, respectively.

#### Valera s Drug Delivery System

Human implantable drug delivery is a relatively new therapeutic drug delivery approach in which drugs are administered directly into the circulatory system through a biocompatible, non-toxic device. Valera believes this type of drug delivery is suitable for certain drugs that are not amenable to oral delivery, such as therapeutic peptides that are destroyed in the gastro-intestinal (GI) tract, or drugs poorly absorbed by the GI tract or destroyed in the liver. In such cases, increasing the dosage of these drugs to increase absorption may result in harmful side effects. As a result, Valera believes that implantable drug delivery systems may provide safer and more effective administration of therapy by delivering the drug directly to the bloodstream at even, controlled rates.

Hydron Technology, Valera's proprietary drug delivery technology, is the basis of Valera's patented hydrogel implant, which is inserted under a patient's skin. This technology, which evolved from similar technology used in soft contact lenses, is flexible and can be adapted to deliver many types of drugs. Currently, Valera only has FDA approval for Vantas. Valera will need to obtain approval for each product Valera develops, including products using Hydron Technology. Valera's implant is designed to allow release of drugs continuously, at even, controlled rates for up to a 12-month period. Valera believes that such predictable release over a period of 12 months has not been achieved by most other drug delivery systems, including sustained release injections, bioerodible implants and transdermal devices. In addition, implants utilizing Hydron Technology are smaller, softer and more flexible than other implants and eliminate the requirement of multiple physician visits and repeated injections.

Utilizing Valera's Hydron Technology, Valera is able to manufacture implants to the exact chemical and physical specifications required by the particular drugs to be released. By modifying the geometric characteristics (wall thickness, diameter and length) and the polymer make-up of the implants, Valera can vary the release rates of a broad spectrum of drugs according to the therapeutic levels required for a particular indication. Once filled with an active ingredient, sealed and sterilized, the implant is inserted into a patient in a minor outpatient procedure generally performed in a physician's office. The procedure to insert the implant takes approximately seven to ten minutes. First, the insertion site is swabbed with an antiseptic. Next, the physician injects an anesthetic immediately under the skin in the upper arm along the path where the implant is to be inserted. Then the physician makes a small incision and inserts the implant under the skin. The incision is then closed with adhesive tape and a bandage is applied for one day. Lastly, the patient is given home care instructions and sent home. The physician can easily remove the implant from the body in a similar procedure. The procedure that Valera intends to use for its Supprelin-LA product; however, in Valera's clinical trials for its Supprelin-LA product Valera evidenced physicians using conscious sedation and general anesthesia on some occasions.

Valera believes that the advantages of its Hydron Technology include:

*Increased Patient Compliance*. Valera s Hydron Technology releases drugs for up to a 12-month period. As a result, the need for multiple physician visits and the inconvenience associated with frequent injections are eliminated, reducing the risk that a patient will miss a treatment.

*Adaptability.* Valera s Hydron Technology can be adapted to deliver many types of drugs. In addition, it provides a controlled and even drug release over a period of time that can result in increased efficacy and safety. Currently, Valera only has FDA approval for Vantas. Valera will need to obtain approval for each additional product it develops including products using its Hydron Technology.

*Decreased Cost.* As a result of the reduced number of patient visits to doctors offices, the overall costs associated with such visits, including scheduling, office visit and reimbursement claim costs, are significantly lowered. In addition, the use of Valera's Hydron Technology lessens the administrative burden on private insurance and Medicare by reducing the number of reimbursement claims processed per year.

Finally, since Vantas is based on Valera s Hydron Technology, Valera believes that the regulatory approval of Vantas may be helpful in obtaining approval of its product candidates that utilize this technology.

Valera s Hydron Technology is limited by the amount of drug which can be loaded into an implant due to its small size, the inability of the technology to deliver drugs that are water insoluble, the inability to deliver molecules with a large molecular weight and the need for a minor surgical procedure to insert and remove the implant.

#### Valera s Business Strategy

In addition to increasing sales of Valera's approved product, Vantas, and subject to Valera's proposed merger with Indevus, Valera's goal is to develop, acquire and commercialize products for the treatment of urological and endocrine conditions, diseases and disorders. To achieve this goal, Valera's strategy includes the following key elements:

*Continue to Focus on Urological and Endocrine Conditions, Diseases and Disorders.* Valera intends to continue to focus on the development, acquisition and commercialization of products for the treatment of urological and endocrine conditions, diseases and disorders. Valera s aim is to build its urological and endocrine product portfolio and opportunistically acquire or in-license later-stage urological and endocrine products that are currently on the market or require minimal development expenditures, or have some patent protection or potential for market exclusivity or product differentiation. Valera intends to collaborate with major and specialty pharmaceutical companies to develop and commercialize products that are outside of its core urology and endocrinology focus.

*Develop Proprietary Pharmaceutical Portfolio.* Valera is building a product portfolio based on its Hydron Technology. Valera has demonstrated the utility of its Hydron Technology through Vantas, and Valera believes that it can utilize this technology to bring additional products to market. Valera intends to apply its Hydron Technology to the delivery of drugs with established safety and efficacy profiles to reduce product development risk and speed time to market.

*License its Implant Technology.* Valera has built, and continues to build, a portfolio of intellectual property around its implant technology. Valera intends to make its proprietary technology available for licensing to third parties. Valera may enter into license agreements or collaborative research and development agreements with third parties to develop implant based therapeutics containing new chemical compounds.

*Develop or Acquire New Drug Delivery Technologies.* In addition to its Hydron Technology, Valera intends to continue to evaluate other drug delivery technologies as candidates for in-license, acquisition and development, including various implantable technologies and other drug delivery systems. Valera believes that, by devoting our its resources to continued development of new drug delivery technologies, Valera can develop a broader base that will enable it to deliver a greater variety of drugs than would be possible using a single drug delivery technology.

*Leverage Sales and Marketing Expertise.* Valera will continue to expand its commercialization efforts by leveraging its existing sales and marketing expertise to market new products as they are approved.

*Partner Outside the United States to Reach New Geographic Markets.* To reach markets outside the United States, Valera has pursued a licensing strategy, whereby it has partnered with companies with a local presence and distribution channels in the urology and endocrinology markets for distribution of its products. Valera may retain full or co-marketing rights, however, on a select territory-by-territory basis to further leverage its sales and marketing expertise.

#### Sales, Marketing and Distribution

As of January 15, 2007, Valera and its co-marketing partner, Indevus, had 105 product specialists promoting Vantas. Valera s product specialists have a substantial number of years of pharmaceutical sales experience and the majority of Valera s sales force has sold other LHRH agonist products prior to joining Valera. Each product specialist is responsible for marketing Vantas to physicians in an assigned geographic territory. At present, Valera is calling on the urologists that account for the majority of LHRH agonist products in the United States. Valera continues to analyze physician prescribing habits so that it can direct its product specialists to physicians who maintain the largest prostate cancer practices. By adjusting its current sales force structure slightly, Valera will be able to call on its current physician base and on physicians in additional specialty areas, such as pediatric endocrinology. Further, Valera believes that the direct physician distribution channel of Vantas may present a barrier to the future entry of competition from generic products because generic drug companies do not typically have a field sales force.

Valera s product specialists utilize various promotional materials when making clinical presentations, including, instructional videos on proper implantation technique. In remote areas where Valera s product specialists cannot productively make personal visits, Valera conducts direct mail programs. Valera also supplies physicians, health plan administrators and specialty pharmacies with a pharmaco-economic model to demonstrate the cost effectiveness of Vantas compared to other LHRH agonist products due to decreased utilization of staff time for repeated injections and one reimbursement claim per patient per year as opposed to three or four.

Additionally, Valera supports its sales efforts by employing a wide range of marketing programs to promote Vantas, including journal advertising, industry publications, medical educational conferences and Internet initiatives. Valera holds meetings in major cities where a Vantas clinical investigator presents data about Vantas, relates his own impressions and demonstrates proper implantation technique. In addition, Valera s product specialists utilize local thought leaders as peer influence speakers in their specific markets.

In addition to product specialists, Valera utilizes the services of Besse Medical, an authorized specialty distributor of Vantas. Besse Medical is responsible for services customarily provided by a wholesale distributor, including the stocking, packing and shipping of Valera s products and is paid a distribution service fee based on the purchases of Vantas through Besse Medical. Valera has also contracted with specialty pharmacies such as Medmark, CuraScript, BioScrip, Caremark and Aetna Specialty to sell Valera s Vantas product through their organizations.

Outside the United States, Valera has primarily pursued a licensing strategy, whereby Valera has partnered with companies with a local presence and distribution channels in the urology or other market for distribution of Vantas or other products Valera may offer. Valera may retain co-marketing rights, however, on a select territory-by-territory, basis. For example, Valera has executed an agreement with Paladin Labs, Inc., a Canadian company, under which it will distribute Vantas in Canada, and has signed similar agreements with each of Key Oncologics (Pty) Ltd., a South African company, BioPro Pharmaceutical, Inc., an organization specializing in marketing oncology drugs in the pan Asian region, Teva-Tuteur, an organization specializing in marketing oncology drugs in Argentina and Spepharm Holding B.V., an organization specializing in urology products in the European Union, Switzerland and Norway. Valera is actively seeking relationships or distribution arrangements with additional GPOs, specialty pharmacies and local companies abroad.

#### Reimbursement

Advanced prostate cancer is generally treated by urologists in their offices. LHRH agonist products are usually sold directly from the pharmaceutical manufacturer to the physician and are administered in the office

through injections or a 12-month implant. Once a physician acquires and administers the LHRH agonist product, the physician files a claim with Medicare or the patient s private insurance for reimbursement.

Approximately 70% of patients diagnosed with prostate cancer and receiving LHRH agonist therapy are over the age of 65 and therefore covered by Medicare. In light of this, Valera has retained a group of Medicare experts to monitor pricing of LHRH agonist products and the Medicare reimbursement environment.

Valera s business is affected by physician utilization, pricing pressure from Valera s competition and Medicare or third party reimbursement, as well as other factors which may cause variances in Valera s revenue. Valera s sales of Vantas from launch in November 2004 through June 30, 2005 were supported, in part, by favorable reimbursement rates, which decreased beginning in the third quarter of 2005. Valera s initial favorable reimbursement rates were due to the fact that Vantas was a new product that did not yet have an established average selling price or ASP, in connection with Medicare reimbursement. As a result, Vantas was reimbursed at wholesale acquisition price, which is typically higher than ASP. Vantas received an established ASP effective July 2005, which resulted in lower reimbursement rates and a corresponding lower sales price to Valera s customers. Valera s historical quarterly net average selling prices to Valera s customers are:

#### Net Average

For the three months ended:	Sell	ling Price
December 31, 2004	\$	2,520
March 31, 2005	\$	2,628
June 30, 2005	\$	2,586
September 30, 2005	\$	2,099
December 31, 2005	\$	1,801
March 31, 2006	\$	1,620
June 30, 2006	\$	1,562
September 30, 2006	\$	1,478
December 31, 2006	\$	1.370

Valera expects future Medicare reimbursement levels to continue to decline for Vantas, which will have an adverse effect on Valera's net product sales. Reimbursement levels are currently set by the twenty-three Medicare carriers in the United States which, in the aggregate, cover all fifty states. Certain Medicare carriers have a policy which sets the reimbursement rate for Vantas based on Valera's ASP. Other Medicare carriers have a policy that applies the least costly alternative, or LCA, methodology to Vantas. LCA is a payment methodology that allows Medicare carriers to pay the same reimbursement for drugs that have been determined by Medicare to be medically equivalent. Vantas is currently the least costly alternative in the class of LHRH drugs. Further, certain Medicare carriers have a policy which segregates twelve-month products from all other dosages, including one, three, four and six month injectable products, and reimburses at different rates for these two groups of products, sometimes referred to as a split policy. Finally, there are certain Medicare carriers which state they have a policy which reimburses on an ASP or LCA methodology, but which Valera believes make payments based upon a split policy.

Valera is devoting internal and external resources to determine the impact and fairness of these various policies. In the states where certain Medicare carriers have adopted a split policy, whether in writing or in practice, Valera is at an economic disadvantage to the injectable products which are reimbursed at higher annual rates. Valera is challenging the basis for these reimbursement policies with the Medicare carriers. Valera will deploy its sales resources in markets where it can sell its products on an even par with the other products in the class. Nevertheless, Valera expects its net product sales to continue to decline in the foreseeable future as a result of the declining reimbursement rates for Vantas.

Valera is also pursuing a sales strategy in which Valera will attempt to sell a greater percentage of Vantas to non-Medicare customers. Non-Medicare customers typically pay a greater amount for Vantas than Medicare customers. Thus, selling a greater percentage of Vantas to non-Medicare customers may alleviate the downward pressure on Valera s net average selling price from the Medicare customers.

## **Intellectual Property**

Valera s success will depend in large part on Valera s ability to maintain a proprietary position in its products and product candidates through patents, trade secrets and FDA exclusivity. Valera relies upon patents, trade secrets, know-how and continuing technological innovation to develop and maintain Valera s competitive position. Valera plans to aggressively protect and defend its proprietary position.

As of December 2006, Valera owned three issued United States patents and 24 issued foreign patents relating to Valera's Hydron Technology. Valera owns three pending foreign patent applications relating to its Hydron Technology. Valera's patents and patent applications cover a variety of novel pharmaceutical formulations, methods of use, and processes to manufacture hydrogel polymers and implants incorporating active agents. Within the Hydron Technology patent portfolio, Valera owns two issued United States patents and 23 issued foreign patents relating to Vantas.

The following table sets forth information related to United States and foreign patents and patent applications owned by Valera:

<b>Technology Family</b> Water-Swellable Hydrophilic Articles	<b>Brief Description of Coverage</b> Method of preparing a hydrophilic plastic cartridge	No. of Patents 15	No. of Pending Applications ()	Date of Grant/ Expiration 1994/2011
Homogenous Hydrogel Copolymers	Method of preparing homogeneous copolymers having a predetermined equilibrium water content value	10	0	1993/2010
Hydrogel Composition	Method of preparing homogenous porous hydrogel	2	3	2002/2020
Implanting Device	Device for inserting implantable objects under the skin	0	17	Not Applicable/ 2023
Implanting Device Design	Design for an implanting Device	5	0	2004/2017
Compositions and Treatments for Central Precocious Puberty	Controlled delivery of gonadotropin-release hormone agonists for the treatment of central precocious puberty	0	3	Not Applicable/ 2025
Polyurethane Implant Formulations	Polyurethane implant formulations and methods of preparing	0	8	Not Applicable/ 2024
Total		32	31	

As noted in the chart above, Valera has filed a United States and two foreign patent applications covering pharmaceutical formulations, processes and methods of use relating to Supprelin-LA. In addition, as of December 2006, Valera also owned five other issued patents and have approximately 25 other patent applications pending worldwide relating to other areas, including implanting devices and designs thereof and polyurethane based implants.

Valera s commercial success will depend in part on obtaining this patent protection. Other intellectual property and know-how, including the Hydron Technology, that Valera has produced and owns, are safeguarded through copyrights, trademarks, trade secret protections and contractual safeguards such as confidentiality and proprietary information agreements. The development of Valera s technology and many of Valera s processes are dependent upon the knowledge, experience and skills of key scientific and technical personnel. To protect Valera s rights to this proprietary information and technology, which are not patentable, Valera requires all employees, consultants and advisors to enter into confidentiality agreements that prohibit the disclosure of

confidential information to anyone outside Valera. As a matter of company policy, all scientific employees are hired to invent and all have executed agreements that recognize this policy and generally require disclosure and assignment to Valera of ideas, developments, discoveries and inventions made by employees. However, these agreements may not effectively prevent disclosure of Valera s confidential information or provide meaningful protection for Valera s confidential information if there is unauthorized use or disclosure.

## **Material Agreements**

In addition to the merger agreement, Valera is a party to certain material agreements including:

## **GP** Strategies Corporation

In June 2000, Valera entered into a contribution agreement with GP Strategies Corporation, Valera's former parent. Under this contribution agreement, GP Strategies contributed, assigned, transferred and conveyed to Valera the assets of GP Strategies drug delivery business, including all intellectual property and certain agreements with Hydron Technologies, Inc., formerly known as Dento-Med Industries, Inc., The Population Council, Inc., and Shire US, Inc., successor to Roberts Laboratories Inc.

Valera assumed all assets, liabilities and obligations of GP Strategies relating or arising from the operation of the drug delivery business and the assets.

## Hydron Technologies, Inc.

In November 1989, GP Strategies Corporation, which was then known as National Patent Development Corporation, entered into an agreement with Dento-Med Industries, Inc., now known as Hydron Technologies. Under the contribution agreement in June 2000 between Valera and GP Strategies, GP Strategies transferred its rights and obligations under the agreement with Hydron Technologies to Valera.

Under the agreement, Hydron Technologies was granted an exclusive, worldwide license, with the right to grant sublicenses, in and to presently owned or subsequently issued patents and the Hydron trademark, to manufacture, market or use products composed of the Hydron polymer or produced with the use of the Hydron polymer in certain consumer and oral health fields, excluding prescription and non-prescription drugs. The agreement purports to continue indefinitely, unless terminated earlier by the parties. Valera has the exclusive right to manufacture, sell or distribute any prescription drug or medical device as defined under the Federal Food, Drug and Cosmetic Act made with the Hydron polymer, however, Valera will not have the right to sell or distribute any Hydron polymer product in the oral health field, except for prescription drug products for lip sores and oral ulcers. Valera also has the exclusive right to manufacture, sell or distribute certain other excepted Hydron products from Hydron Technologies license. Neither party is prohibited from manufacturing, exploiting, using or transferring the rights to any new non-prescription drug product containing the Hydron polymer, subject to certain exceptions, for limited exclusivity periods.

In the event Valera withdraws from the business of manufacturing the Hydron polymer, Valera will assign all of its right and interest in the Hydron trademark to Hydron Technologies. Upon request from Hydron Technologies, Valera may provide certain research services, including limited use of Valera's facilities, for Hydron Technologies research activities, for which Valera will be reimbursed a specified amount. In addition, subject to certain conditions and exceptions, Hydron Technologies has the right to purchase from Valera and Valera is obligated to supply to Hydron Technologies certain types of Hydron polymers.

Subject to certain exceptions (including Vantas and Supprelin-LA), each party will pay to the other a 5% royalty on net sales for Hydron polymer products marketed by Valera or Hydron Technology, as applicable, or a third party. Valera s Naltrexone and Octreotide implants would be subject to the 5% royalty to be paid to Hydron Technology. Subject to certain excepted Hydron polymer products, in the event either party sells any non-prescription Hydron polymer drug products itself, such party will pay a 5% royalty fee on net sales,

including research payments, to the other party. Subject to certain Hydron polymer excepted products, if either party sells non-prescription drug products to a third party and receives up-front license fees, royalties or similar payments, such party will pay a 25% royalty on such payments to the other.

## The Population Council

In September 1990, GP Strategies Corporation, which was then known as National Patent Development Corporation entered, into a joint development agreement with The Population Council regarding the development of hydrogel implants containing LHRH. Under the contribution agreement entered into in June 2000 between Valera and GP Strategies, GP Strategies transferred its rights and obligations under the agreement with The Population Council to Valera.

By amendment to the agreement dated October 1, 1997, the Joint Development Agreement was terminated in its entirety and superseded by the terms and conditions of the amendment. Under the amendment, The Population Council concluded all ongoing prostate cancer clinical studies and provided Valera with all data and records relating to those trials to enable Valera to advance the clinical trials and seek regulatory approval to commercially develop and market any polymer implant containing any LHRH analog or any polymer implant containing any other active agent, other than an LHRH analog. Valera can enter into licensing and marketing agreements for the commercial development of those implants without the consent of The Population Council receives approximately \$40 million in payments from Valera. Either party may terminate the agreement if the other party becomes insolvent or is involved in bankruptcy proceedings or if, after receiving written notice the other party is in default of a material term and such default has not been cured within thirty days of the notice.

By a further amendment to the agreement dated August 2004, The Population Council is entitled to 30% of certain revenues received by Valera from the licensing of Vantas or any other polymer implant containing an LHRH analog and 5% of certain revenues received by Valera from the licensing of any other polymer implant to the extent those revenues are related to the use or sale of implants in all areas other than the European Union and certain Southeast Asian countries. Valera is required to pay to The Population Council 3% of Valera s net sales of Vantas and any polymer implant containing an LHRH analog and 0.5% of Valera s net sales of any other polymer implant. The Population Council is also entitled to 4% of any licensee s net sales of Vantas and any other polymer implant containing an LHRH analog within the European Union and certain Southeast Asian countries and 0.667% of any licensee s net sales for any other polymer implant within the European Union and certain Southeast Asian countries. In addition, Valera is required to establish a patient assistance program within one year after the first commercial sale of Vantas in the United States and maintain the program for a period ending on the earlier of ten years after establishment of the program or the cessation of the marketing of Vantas.

## Shire Pharmaceuticals Group plc

In March 1998, GP Strategies entered into a license agreement and a related manufacturing and supply agreement with Roberts Laboratories Inc. under which Roberts was responsible for conducting Phase III clinical trials, managing the regulatory approval process and marketing the product now known as Vantas. When Roberts was acquired by Shire Pharmaceuticals Group in December 1999, Shire took over the development of Vantas. In December 2001, Valera entered into a termination, license back and option agreement with Shire US, a subsidiary of Shire Pharmaceuticals Group, which terminated and released all claims of the parties under the previous license and manufacturing agreements. Under this agreement, Shire transferred to Valera all on-going activities under the development program for Vantas, including all data, know-how and other information with respect to Vantas generated in connection with the development program, and granted Valera an exclusive license to such data, know-how and information for the development, manufacture, use, supply and sale of Vantas in the designated territory, including, but not limited to, the United States, Canada, and various European and other countries. In December 2006, Valera agreed to amend the definition of territories within the termination, license back and option agreement with Shire US to include the Republic of Ireland.

The term of the license continues for ten years from the date of the first commercial sale of Vantas. Thereafter, Valera will have a fully paid up license in the designated territory with respect to all data, know-how and other information related to Vantas generated under Shire s previous development program for Vantas.

Valera is required to pay Shire 2% of net sales of Vantas in the designated territory. However, for the purposes of this agreement, net sales are reduced by the amount of any royalty payments Valera makes to The Population Council with respect to sales of Vantas. If Valera sublicenses Vantas to another entity in the designated territory, Valera will pay Shire fees of 20% of royalty income and 20% of any milestone payments Valera receives, up to a maximum of \$5 million, relating to any sublicensing of Vantas. Royalty income does not include amounts paid to The Population Council with respect to sales of Vantas by a sub-licensee. However, the \$5 million cap on Valera s royalty s payments with respect to milestone payments is only applicable if Valera is entitled to receive at least 10% of net sales under the sublicense agreement.

Valera also granted Shire an exclusive, irrevocable option, on a country-by-country basis in the designated territory, to exclusively market and distribute Vantas in each country of the designated territory, other than in the United States. This option, with respect to each country, will expire on the earlier of the date Valera enters into a sublicense agreement for that particular country or 180 days following the date of regulatory approval in that particular country for Vantas. Valera may market Vantas in any country at the expiration of the option with respect to that country. If Shire exercises the option with respect to a particular country, Valera will supply Vantas at the cost of manufacture. Shire will pay Valera 13.5% of its net sales within the option territory. Each marketing and distribution arrangement requested by Shire under its option will have a term of 10 years. Shire has not exercised its right to market Vantas in any of the countries that Valera has entered into a sublicense agreement or received regulatory approval. Either party may terminate if either party becomes insolvent or there is a material breach of the agreement.

## Paladin Labs, Inc.

In October 2002, Valera entered into a license and distribution agreement with Paladin Labs under which it granted Paladin Labs an exclusive, royalty bearing license under Valera s intellectual property, including Valera s patents, trademarks and know-how, to seek regulatory approval for the marketing, distribution and sale in Canada and its territories of (i) Vantas for the treatment of prostate cancer and (ii) any other Hydron histrelin implant, which is, or may be, developed by Valera for other indications, such as Supprelin-LA, Valera s histrelin implant for CPP. Paladin Labs is obligated to use commercially reasonable efforts to apply for and maintain regulatory approval for Vantas and any other Hydron histrelin implant and to sell, market and distribute those implants in Canada and its territories. The initial term of the agreement is for fifteen years from March 2006, the date on which regulatory approval for Vantas in Canada was obtained, and will automatically renew for subsequent three year terms, unless terminated earlier. Either party may terminate the agreement if the other party becomes insolvent or is involved in bankruptcy proceedings, or if, after receiving written notice the other party commits a material breach that has not been cured within thirty days of the notice or the other party is unable to fully perform its obligations as a result of a force majeure event. Valera also granted Paladin Labs an exclusive license to use the trademarks owned by Valera, including all trademarks and trade names approved by Valera, in connection with the marketing, distribution and sale of Vantas or any other Hydron histrelin implant in the designated territory. Valera has given Paladin Labs the exclusive right, but not the obligation, to conduct Phase IV clinical trials relating to the use of Vantas for the treatment of prostate cancer in the designated territory. If Paladin Labs does not conduct such trials within one year of Valera 's request to do so, Valera will have the right to conduct such Phase IV c

Valera has the sole right and responsibility for the manufacturing, assembling, packaging and labeling of Vantas or any other Hydron histrelin implant in such quantities required for Paladin Labs demand forecast and Valera must use all reasonable efforts to supply those products. In addition, Paladin granted Valera a non-exclusive license to use its trademarks on labeling of Vantas or any other Hydron histrelin implant. Valera has agreed not to supply Vantas or any other Hydron histrelin implant for distribution or sale in Canada and its

territories for use in any indication to any other party except Paladin Labs. Paladin Labs will pay Valera a flat transfer fee of \$190 per unit and a royalty of 8% of its net sales of Vantas or any other Hydron histrelin implant.

Under the terms of the agreement, Valera and Paladin have agreed not to develop, market, distribute or sell in Canada or its territories any products that contain the same active ingredient as that which is contained in Vantas, or any products similar to or competitive with Vantas or any other Hydron histrelin implant approved in Canada during the term of the agreement and for a period of three years following the expiration or termination of the agreement; provided that Valera is permitted to make, market, distribute and sell Vantas in the designated territory for all indications following the expiration or termination of the agreement.

## Key Oncologics (Pty) Ltd.

In September 2003, Valera entered into a license and distribution agreement with Key Oncologics, under which Valera appointed Key Oncologics as the exclusive agent to apply for regulatory approval for and distribute Vantas in South Africa and its territories for use in the treatment of prostate cancer. The initial term of the agreement is for five years after the date on which regulatory approval for Vantas for the treatment of prostate cancer is obtained in South Africa, subject to automatic one-year renewal periods unless terminated earlier. Either party may terminate the agreement if the other party becomes insolvent or is involved in bankruptcy proceedings, or if, after receiving written notice, the other party commits a material breach that has not been cured within thirty days of the notice or the other party is unable to fully perform its obligations as a result of a force majeure event. Key Oncologics may terminate the agreement if regulatory approval of Vantas for the treatment of prostate cancer is finally denied by South Africa s regulatory authority. Terminations with respect to one or more, but not all forms or dosages, will only apply to the affected forms or dosages. Key Oncologics is obligated to use commercially reasonable efforts to apply for and maintain regulatory approval in South Africa.

Valera has agreed to supply Vantas, as well as containers for and components of Vantas, to Key Oncologics exclusively in South Africa. Valera is obligated to supply Key Oncologics with all data and information in Valera's possession or control as is necessary for the purpose of obtaining regulatory approval of Vantas for use in the treatment of prostate cancer in South Africa. Valera gave Key Oncologics the exclusive right, but not the obligation, to conduct Phase IV clinical trials relating to the use of Vantas for the treatment of prostate cancer in the designated territory. If Key Oncologics does not conduct such trials within one year of Valera's request to do so, Valera will have the right to conduct such Phase IV clinical trials on its own. Valera will receive a perpetual, fully-paid, royalty-free license to use any data developed by Key Oncologics in the Phase IV trials.

Under the terms of the agreement, Key Oncologics has agreed not to develop, market, distribute or sell in South Africa any products that contain the same active ingredient contained in Vantas, or any products similar to or competitive with Vantas that are used to treat prostate cancer during the term of the agreement and for a period of three years following the expiration or termination of the agreement, except that Key Oncologics may market, distribute and sell a certain product under a previous third party license agreement.

Valera has granted Key Oncologics an exclusive license to use Valera s trademarks owned by Valera, including all trademarks and trade names approved by Valera, in connection with the marketing, distribution and sale of Vantas in South Africa in connection with the treatment of prostate cancer. Key Oncologics has granted Valera a non-exclusive license to use Key Oncologics trademarks on labeling of Vantas. Valera has the sole right and responsibility for manufacturing, assembling, packaging and labeling Vantas and Valera is required to supply Vantas in sufficient quantities to meet Key Oncologics demand forecast. Valera has agreed not to supply Vantas for distribution or sale in any of the designated countries for use in the treatment of prostate cancer to any other party except Key Oncologics. For a period of twelve months following the receipt of regulatory approval, Key Oncologics will pay Valera a flat transfer fee of \$250 per unit of Vantas, plus 10% of the net sales collected by Key Oncologics. After the end of the first twelve-month period, Valera will have the right to adjust the price per unit once per year, subject to certain exceptions.

#### BioPro Pharmaceutical, Inc.

In January 2005, Valera entered into an exclusive license and distribution agreement with BioPro. The initial term of the agreement is for ten years after the date on which the first regulatory approval allowing sales of Vantas to proceed in any country of the designated territory is issued, unless terminated earlier and automatically renews for additional periods of one year unless notice of termination is given. Either party may terminate the agreement if the other party becomes insolvent or is involved in bankruptcy proceedings, or if, after receiving written notice, the other party commits a material breach that has not been cured within thirty days of the notice or the other party is unable to fully perform its obligations as a result of a force majeure event. Either party may terminate the agreement on a country-by-country basis if regulatory approval of Vantas for the treatment of prostate cancer is finally denied by the regulatory authority within that country. Terminations with respect to one or more, but not all, forms, dosages, countries or indications will apply to the affected forms, dosages, countries or indications. Additionally, Valera may terminate the agreement if BioPro fails to achieve minimum net sales and then fails to make minimum required payments to Valera, or Valera may terminate the agreement on a country-by-country basis and on an indications-by-indications basis if BioPro fails to file necessary marketing approval applications.

Under the agreement, BioPro will be the exclusive distributor of Vantas in the designated territory consisting of Brunei, Cambodia, China (including Hong Kong), Laos, India, Indonesia, Malaysia, the Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam. BioPro is required to use commercially reasonable efforts to apply for and maintain regulatory approval for Vantas for the treatment of prostate cancer in the designated territory. In connection with obtaining regulatory approval for Vantas, Valera is required to supply BioPro with all data and information in Valera s possession or control as is necessary for that purpose. Valera also granted BioPro an exclusive license to use the trademarks owned by Valera, including all trademarks and trade names approved by Valera, in connection with the marketing, distribution and sale of Vantas in the designated territory. Valera gave BioPro the non-exclusive right, but not the obligation, to conduct Phase IV clinical trials relating to the use of Vantas for the palliative treatment of prostate cancer in each country of the designated territory. BioPro has applied for regulatory approval for the commercialization of Vantas in Thailand, Singapore, Malaysia, Taiwan, Korea, Hong Kong and China.

BioPro granted Valera the right to use BioPro s trademarks on labeling of Vantas. Valera has the sole right and responsibility to manufacture, assemble, package and label Vantas and is required to supply Vantas in quantities sufficient to meet BioPro s demand forecast. Valera has agreed not to supply Vantas for distribution or sale in any of the countries in the designated territory for use in any indication to any other party except BioPro. BioPro will pay Valera a flat transfer fee of \$250 per unit and a royalty of 25% of net sales of Vantas, in addition to various milestone payments. BioPro must pay Valera a minimum amount if it fails to achieve certain minimum net sales. In addition, BioPro is obligated to pay a royalty of 2% of net sales of Vantas directly to The Population Council or a minimum payment if certain minimum net sales are not achieved. Twelve months following the first commercial sales of Vantas in the designated territory, Valera will have the right, subject to certain exceptions, to adjust the price per unit once per year.

Affiliates of Sanders Morris Harris, Inc., of which James Gale, the Chairman of Valera s board of directors, is a managing director, own approximately 40% of BioPro. Affiliates of Sanders Morris Harris, Inc. own approximately 37% of the outstanding common stock of Valera.

## Alpex Pharma S.A.

In April 2005, Valera entered into a collaboration and development agreement with Alpex Pharma to research and develop a rapid dissolve desmopressin product. Under the agreement, Valera has an exclusive, royalty-bearing license, based in part on Alpex s intellectual property, including the right to sublicense, to make, use, sell, and otherwise commercialize the rapid dissolve desmopressin product in the United States, Canada, and Mexico. The agreement continues in effect until the expiration of all Alpex patents related to Alpex s platform technology that cover the rapid dissolve desmopressin product. Upon expiration of all Alpex patents related to

Alpex s platform technology that cover the rapid dissolve desmopressin product, Valera will have a fully paid-up, royalty-free, non-exclusive, irrevocable license, including the right to sublicense, to make, use, sell, and otherwise commercialize the product in the United States, Canada and Mexico.

Under the agreement, Alpex is obligated to use commercially reasonable efforts to diligently perform its obligations under the agreement, including developing the rapid dissolve desmopressin product. Valera is obligated to use commercially reasonable efforts to perform its obligations under the agreement, including to obtain and maintain all regulatory approval for the rapid dissolve desmopressin product in the United States, Canada, and Mexico. If Valera does not file for regulatory approval in the United States within six months after satisfaction of certain product success criteria, as agreed upon by Valera and Alpex, Alpex may elect to transform Valera s license into a non-exclusive, royalty-free license. Alpex is required to make all intellectual property and technical information available to Valera as may reasonably be necessary for regulatory approval. Alpex owns all intellectual property related to the platform technology, and will own any intellectual property developed pursuant to the collaboration that relates to the platform technology. Valera will own all intellectual property related to the rapid dissolve desmopressin product in the United States, Canada and Mexico. Alpex will own all intellectual property related to the rapid dissolve desmopressin product in the United States, Canada and Mexico.

Valera is obligated to use its commercially reasonable efforts to market, distribute and sell the rapid dissolve desmopressin product in the United States, Canada and Mexico. Alpex has agreed not to, directly or indirectly develop, market, distribute or sell a product that contains desmopressin in the United States, Canada or Mexico. Alpex shall manufacture and supply sufficient quantities of the rapid dissolve desmopressin product for clinical trials and commercial sale to meet Valera s needs. Both parties must use best efforts to enter into such a manufacturing and supply agreement prior to the first commercial shipment of the rapid dissolve desmopressin product.

Valera may terminate the agreement and obligations of the parties if Valera determines, in its sole discretion, that the development and/or commercialization of the rapid dissolve desmopressin product has been impaired due to (i) difficulties in development or formulation; (ii) unfavorable action by the FDA; (iii) likelihood of failure to obtain regulatory approval; (iv) concerns of possible third party infringement; and (v) unfavorable market conditions for the rapid dissolve desmopressin product. In the event Valera discontinues the development and/or commercialization of the product, Alpex may continue or resume the development and/or commercialization of the rapid dissolve desmopressin product, provided that it reimburses Valera for at least a portion of its development costs, including any license or milestone payments.

Valera is required to pay Alpex one-time milestone payments related to the development of the rapid dissolve desmopressin product and lump-sum payments upon regulatory filing in the United States and upon approval in the United States. Valera is also required to pay Alpex a range of royalty payments based on net sales of the rapid dissolve desmopressin product and a percentage of all sublicensing income. Valera s royalty payment obligations will expire twenty years from the date of the first commercial shipment of the rapid dissolve desmopressin product, and the license will become a royalty-free, non-exclusive, perpetual, worldwide license to make, have made, use, import, export, sell, offer to sell and otherwise commercialize the rapid dissolve desmopressin product in the United States, Canada and Mexico.

James Gale, the Chairman of Valera s board of directors, is also on the board of directors of Alpex. Affiliates of Sanders Morris Harris, Inc., of which Mr. Gale is a managing director, own approximately 37% of the outstanding common stock of Valera and more than 90% of the outstanding capital stock of Alpex.

## Teva-Tuteur

In December 2005, Valera entered into an exclusive distribution agreement with Teva-Tuteur for distribution of Vantas in Argentina. The initial term of the agreement ends on the date that is ten years after the date on which the first regulatory approval allowing sales of Vantas to proceed in Argentina is granted, unless terminated earlier. The agreement automatically renews for additional periods of one year each unless notice of

termination is given. Either party may terminate the agreement if the other party becomes insolvent or is involved in bankruptcy proceedings or if the other party fails to cure a material breach within a specified time period after receipt of notice or the other party is unable to fully perform its obligations for one hundred-fifty days as a result of a force majeure event. Either party may terminate the agreement on an indication-by-indication basis if regulatory approval of Vantas for such indication is finally denied by the regulatory authority within Argentina. Terminations with respect to one or more, but not all, forms, dosages or indications will apply to the affected forms, dosages or indications. Additionally, Valera may terminate the agreement if Teva-Tuteur fails to purchase a specified number of units of Vantas in a calendar year. Valera may also terminate the agreement on an indications-by-indications basis if Teva-Tuteur fails to file necessary marketing approval applications within the required time.

Under the agreement, Teva-Tuteur will be the exclusive distributor of Vantas in Argentina. Teva-Tuteur is required to use commercially reasonable efforts to apply for and maintain regulatory approval for Vantas in Argentina for each indication for which Valera owns or holds a regulatory approval anywhere in the world. In connection with obtaining regulatory approval for Vantas, Valera is required to supply Teva-Tuteur with all data and information in Valera s possession or control as is necessary for that purpose. Valera also granted Teva-Tuteur an exclusive license to use the trademarks owned and approved by Valera, in connection with the marketing, distribution and sale of Vantas. Valera has given Teva-Tuteur the non-exclusive right, but not the obligation, to conduct Phase IV clinical trials relating to the use of Vantas in each approved indication in Argentina.

Teva-Tuteur granted Valera the right to use Teva-Tuteur s trademarks on labeling of Vantas. Valera has the sole right and responsibility to manufacture, assemble, package and label Vantas; provided that Teva-Tuteur is responsible for any and all Argentinean-specific labeling. Valera has agreed not to supply Vantas for distribution or sale for use in any indications to any other party except Teva-Tuteur. Teva-Tuteur will pay Valera a flat transfer fee per unit, which fee is subject to an index-based adjustment. Beginning in the first calendar year after the first commercial sale of Vantas in Argentina, Teva-Tuteur must make certain minimum purchases during each calendar year unless it provides written notice one hundred and twenty (120) days prior to the end of any such calendar year, in which case Teva-Tuteur is relieved of the minimum purchase requirement for such calendar year. If Teva-Tuteur provides such notice, Valera has the option to (i) convert the exclusive right granted to Teva-Tuteur into a non-exclusive right effective as early as the date of the receipt of such written notice from Teva-Tuteur or (ii) terminate the agreement effective as early as the date of the receipt of such written notice from Teva-Tuteur.

## Valstar<sup>®</sup> (Valrubicin)

In March 2006, Valera completed the acquisition of certain assets of Anthra associated with its valrubicin business in the United States and Canada. Anthra s valrubicin business involved the manufacture and sale of valrubicin for use in the treatment of bladder cancer. The product was distributed in the United States and Canada by third party partners of Anthra. In the United States, the product was distributed under the trademark Valstar. The product is not covered by any patents and its orphan drug status has expired.

Anthra s valrubicin product was taken off the market in 2002 due to a manufacturing problem and a lack of resources to address the problem. Valera has analyzed the manufacturing issues and believes that it has determined the cause of, and a solution to, the problem. As such, Valera acquired certain assets of Anthra required for the manufacture, marketing and sale of valrubicin in the United States and Canada including the NDA filed with the FDA, the drug master file, the Canadian regulatory submission and all data produced by or on behalf of Anthra in support of the NDA and other governmental approvals, or in any other scientific experiment or clinical trial relating to valrubicin.

The purchase price payable for the product consists of guaranteed payments, totaling approximately \$0.6 million, revenue sharing payments of up to 13.5% of Valera s sales and receipt of license fees and additional

payments based on Valera s sales performance. Subject to certain exceptions, Anthra s indemnification obligations survive for two years after closing and are funded by setoff against the purchase price payable to Anthra under the agreement.

## Plantex

On May 17, 2006, Valera entered into a supply agreement with Plantex USA Inc. whereby Plantex would supply Valera with the active pharmaceutical ingredient N-Trifluroacetyl-adriamycin-14 valerate, otherwise known as Valrubicin (API), in connection with Valera s anticipated launch of the product Valstar for the treatment of bladder cancer. Under the Agreement, Valera will only source API from Plantex in connection with the development, manufacture or sale of, and securing regulatory approval for, Valstar in the United States, its territories and possessions, and Canada (the Territory). Subject to certain minimum purchase requirements by Valera, Plantex will manufacture and supply all of Valera s requirements for API for commercial sale of Valstar in the Territory. Valera is obligated to use commercially reasonable efforts to obtain regulatory approval in the Territory to manufacture the finished product. Plantex will also be required to obtain and maintain all regulatory approvals necessary for its manufacturing obligations under the Agreement. It is intended that API supplied by Plantex will be shipped to another manufacture for manufacturing, packaging and labeling of the finished product.

The Agreement will expire ten years after the date of the first commercial sale of Valstar by or on Valera's behalf to an independent third party in the Territory. The Agreement will automatically renew for successive two year periods unless either party provides the other with written notice of its intention not to extend the term of the Agreement at least twelve months before the expiration of the initial term or any renewal term. In addition, the Agreement is subject to termination if: (i) a party commits a breach that has not been cured within thirty days of the notice in the case of a payment default or within ninety days notice in all other cases; (ii) the parties mutually agree to terminate the Agreement; (iii) a party is unable to fully perform its obligations as a result of a force majeure event; (iv) a party becomes involved in bankruptcy proceedings; or (v) Valera fails to obtain regulatory approval of supplementary chemistry, manufacturing and control filings necessary for the launch of Valstar prior to June 30, 2007. Under the terms of the agreement, beginning in the calendar year following the year in which Valera receives regulatory approval for Valstar in the United States, Valera will be required to purchase a minimum of \$1,000,000 of Valrubicin each calendar year until the agreement expires.

## Spepharm Holding B.V.

On July 17, 2006, Valera entered into an Investment and Shareholders Agreement in which Valera received a 19.9% ownership interest in a newly created Dutch company called Spepharm Holding B.V., or Spepharm, for a nominal amount of approximately EUR 3,675 (approximately \$4,500) and product distribution rights. The other investors in Spepharm include TVM Life Science Ventures VI L.P., TVM Life Science Ventures VI GmbH & Co. KG, Life Sciences Opportunities Fund (Institutional) II, L.P., Life Sciences Opportunities Fund II, L.P., ARCADE SARL, and Jean-François Labbé, or, collectively, the Investors. The shareholders agreement provides a provision for two subsequent capital increases if additional funding is required by Spepharm. Upon the request and approval of the subsequent capital increase, Valera will have the option to purchase at a nominal value, 19.9% of the entire new shares being offered in the capital increase, thus giving Valera the option to keep its 19.9% ownership interest in Spepharm and its European specialty pharmaceutical group of companies are focusing on becoming one of the leading suppliers of specialty urology and endocrinology products to the European market place.

In addition to the 19.9% ownership in Spepharm, Valera entered into a License and Distribution Agreement with Spepharm. Under the terms of the distribution agreement, Valera will give Spepharm the exclusive licensing and distribution rights to Valera s products under the trademark Vantas and Supprelin-LA, which are referred to in the distribution agreement as the Products, in the European Union as well as Norway and Switzerland for a period of ten years. Valera will supply Spepharm with the Products on an exclusive basis in the territory prior to

regulatory approval and following receipt of regulatory approval, for distribution and sale in the territory for the use in each indication, as that term is defined in the distribution agreement. Under the terms of the distribution agreement, Valera will assign to Spepharm all marketing approval applications and any regulatory approval held by Valera with respect to the Products. Spepharm, at its own expense, will be required to use commercially reasonable efforts to apply for and maintain regulatory approval for each Product in each country of the territory for use in each indication. In connection with obtaining regulatory approval for the Products, Valera will be required to supply Spepharm with all data and information in its possession or control as is necessary for that purpose. Valera will also grant Spepharm an exclusive license to use the trademarks owned by Valera, including all trademarks and trade names approved by Valera, in connection with the marketing, distribution and sale of each Product in the territory for each indication. Valera will give Spepharm the non-exclusive right, but not the obligation, to conduct Phase IV clinical trials relating to the use of the Products in each indication in each country of the territory, but only with Valera s prior written consent. Spepharm will grant Valera the right to use Spepharm s trademarks on labeling of the Products. Valera will have the sole right and responsibility to manufacture, assemble, package and label the Products and will be required to supply the Products in quantities sufficient to meet Spepharm s forecast. For a period of five years from the date of the distribution agreement, Spepharm will be prohibited from directly or indirectly developing, marketing, distributing or selling in any country in the territory any Products, any products similar to or competitive with any Product, or any products that are used in any Indication. Spepharm will pay Valera for our supply and Spepharm s distribution of the Products under the distribution agreement an aggregate amount equal to forty percent (40%) of Net Sales, which is referred to in the distribution agreement as the Royalty Amount, based on an established transfer price. In addition, within thirty (30) days following the end of each calendar quarter, Spepharm will pay Valera an amount equal to the difference between (a) the aggregate Royalty Amount for such calendar quarter minus (b) the aggregate transfer prices paid by Spepharm during such calendar quarter. In addition, according to the terms of the distribution agreement, Spepharm will be required to achieve certain Minimum Net Sales, as defined in the distribution agreement. If Spepharm fails to achieve the Minimum Net Sales in a given calendar year with respect to a Product, then Spepharm will pay Valera an amount equal to (i) the difference between Minimum Net Sales for such Product for such calendar year minus the actual amount of Net Sales of the Product for such calendar year multiplied by (ii) forty percent (40%), less the amount of the aggregate transfer prices paid by Spepharm during such calendar year to the extent such transfer prices have not been taken into account for the purposes of determining the Royalty Payment. Spepharm may notify Valera no later than forty-five (45) days after the completion of the calendar year that it will not pay the amounts required by the Minimum Net Sales provision for the just completed calendar year, in which case, Spepharm shall be relieved from its obligation to pay the amount required. In such event, Valera will have the right either (i) to convert all of the exclusive rights granted to Spepharm in the distribution agreement with respect to such Product into non-exclusive rights effective as of the date of Spepharm s notice to Valera or such later date as Valera may specify or (ii) to terminate the distribution agreement with respect to such Product effective as of the date of Spepharm s notice to Valera or such later date as Valera may specify. If Spepharm does not send a notice permitted by the distribution agreement or does so after the period specified in the distribution agreement, Spepharm will not be relieved of its obligations under the distribution agreement and failure to pay such obligation will be considered a Material Breach, as defined in the distribution agreement.

In accordance with the shareholders agreement, David S. Tierney, M.D., Valera's President and Chief Executive Officer and Mr. James Gale, Valera's chairman of the board of directors, have been appointed as members of Spepharm's initial supervisory board. LSOFI and LOSF are funds managed by, and affiliates of, Sanders Morris Harris, Inc., or SMH, whose affiliates own approximately 37% of the outstanding common stock of Valera. Mr. Gale is a Managing Director of SMH and the investment manager of such funds that hold shares of Valera and has sole voting and dispositive power over such shares. SMH and TVM Capital, the manager of TVM LP and TVM KG, have committed approximately EUR 20,000,000 to the Spepharm venture.

# Poly-Med

In connection with the Revised Research and Development Proposal dated April 27, 2005, between Valera and Poly-Med, Inc. and the Advanced Development and Pilot Production Outline issued by Valera and Poly-Med

on March 24, 2006 and revised on April 10, 2006, relating to the development of an biodegradable endoureteral stent, on December 4, 2006, Valera entered into a Letter Agreement with Poly-Med, pursuant to which Valera agreed to engage in exclusive negotiations to enter into a license and supply agreement providing Valera with an exclusive license to use and sell the endoureteral stent in exchange for certain royalty payments. The license and supply agreement will also set forth the terms under which Poly-Med will manufacture and supply Valera with the endoureteral stent. The exclusivity period contemplated by the letter agreement expires June 30, 2007.

## Indevus Pharmaceuticals, Inc.

In December 2006, Valera entered into a merger agreement with Indevus pursuant to which Indevus will acquire Valera in a tax-free stock-for-stock merger transaction. Pursuant to the Merger Agreement, upon the closing of the merger, each outstanding share of Valera s common stock (other than shares held by Valera or Indevus or any stockholders who properly exercise appraisal rights under Delaware law), will automatically be converted into the right to receive a number of shares of Indevus common stock equal to \$7.75 divided by the volume weighted average of the closing prices of Indevus common stock during the 25 trading days ending on the fifth trading day prior to the date of the Valera stockholders meeting to consider the merger, or the Indevus Common Stock Value. The exchange ratio is subject to a collar such that if the Indevus Common Stock Value falls outside of the collar the exchange ratio will become fixed. If the Indevus Common Stock Value is greater than \$8.05, then the exchange ratio will be 0.9626, and if the Indevus Common Stock Value is less than \$6.59, then the exchange ratio will be 1.1766. Cash will be paid in lieu of fractional shares. See the sections entitled The Merger Material United States Federal Income Tax Consequences and The Merger Agreement Merger Consideration.

In addition, each share of Valera s common stock will be converted into three contingent stock rights, or CSRs, relating to three of Valera s product candidates. One CSR will be convertible into \$1.00 of Indevus common stock upon FDA approval of Supprelin-LA, provided sufficient quantities of Supprelin-LA are then available, one CSR will be convertible into \$1.00 of Indevus common stock upon FDA approval of Valera s biodegradable ureteral stent and one CSR will be convertible into \$1.50 of Indevus common stock upon FDA approval of Valera s octreotide implant. The amount of Indevus common stock into which the CSRs will convert will be determined by a formula based on the average stock price of Indevus prior to achievement of the applicable milestones. The CSRs will convert into Indevus common stock only if the applicable milestones are achieved within three years of the closing of the merger in the case of Supprelin-LA and within five years of the closing of the merger in the case of Valera s biodegradable ureteral stent and octreotide implant. See the section entitled The Merger Agreement Merger Consideration.

In connection with the merger transaction, certain affiliated funds of Sanders Morris Harris, Valera's largest shareholder, and one other large shareholder of Valera, entered into voting agreements with Indevus in which they have agreed to vote shares representing approximately 41% of Valera's outstanding shares of common stock in favor of the merger. The merger has been approved by Valera's board of directors, as well as Indevus' board of directors. Valera anticipates the merger will close by the end of April 2007. The merger is subject to certain customary closing conditions, including the approval of Valera's stockholders and the approval of Indevus' stockholders. See the section entitled The Merger Agreement Conditions to Completion of the Merger.

James C. Gale, chairman of Valera's board of directors and chief investment officer of the Corporate Opportunities Funds and Life Sciences Opportunities Fund, affiliates of Sanders Morris Harris, is expected to join the Indevus board of directors. Sanders Morris Harris is currently Valera's largest shareholder. Additionally, Dr. David Tierney, Valera's President and Chief Executive Officer, will provide consulting services during a transition period after the completion of the merger transaction. Valera's facility in Cranbury, New Jersey, which contains significant manufacturing operations and research and development capabilities, will be maintained and become an integral part of Indevus' operations.

Separately, in December 2006, Valera entered into a co-promotion agreement with Indevus pursuant to which Indevus sales force will co-promote Vantas in the United States. Under the terms of the agreement,

Valera is required to make royalty payments to Indevus of 13.5% on sales of Vantas up to a specified unit level, which will increase to 30% for sales above the specified level. Indevus will also receive royalties of 35% for sales of Vantas to specified specialty pharmacy accounts. Additionally, the co-promotion agreement provides Valera with the option to elect to enter into negotiations with Indevus to grant Indevus a co-exclusive right to co-promote Supprelin-LA. The co-promotion began in January 2007.

## Competition

The biotechnology and pharmaceutical industries are very competitive. In particular, competition for the development and marketing of urological and endocrine pharmaceutical products is intense and is expected to increase. Many of Valera s competitors have substantially greater financial and other resources, larger research and development staffs and more experience developing products, obtaining FDA and other regulatory approval of products and manufacturing and marketing products. Valera competes against all pharmaceutical companies that manufacture or market LHRH agonist products. In addition, Valera competes against biotechnology companies, universities, government agencies, and other research institutions in the development of urological and endocrine products, technologies and processes that are, or in the future may be, the basis for competitive commercial products.

In particular, Valera competes against the following LHRH agonist products for the palliative treatment of advanced prostate cancer: TAP Pharmaceutical Products Lupron and Sanofi-Aventis Eligard, both multiple injection formulations that deliver leuprolide; Watson Pharmaceuticals Trelstar that delivers triptorelin; AstraZeneca s Zoladex, a biodegradable rod that delivers goserelin for up to three months; and Bayer Pharmaceuticals Viadur, a rigid metal implant that releases leuprolide over a 12-month period. With respect to its Supprelin-LA product in late-stage development for the treatment of CPP, Valera s competitor is TAP Pharmaceutical Products Lupron Depot-PED and with regard to VP003, Valera s octreotide implant for acromegaly, Valera s competitors include Novartis Sandostatin injections and Sandostatin LAR Depots and Pfizer s Somavert. Valera believes that its implantable products represent a more comfortable and convenient alternative to competing products because it eliminates the requirement of multiple physician visits and repeated injections, and is smaller, softer and more flexible than other implants.

## **Regulatory Matters**

## General

The production, distribution and marketing of products employing Valera's technology, and Valera's research and development activities, are subject to extensive governmental regulation in the United States and in other countries. In the United States, Valera's product candidates are regulated as drugs, and are subject to the Federal Food, Drug and Cosmetic Act, the Public Health Service Act and the regulations promulgated under these statutes, as well as to other federal, state and local statutes and regulations. These laws govern the clinical and non-clinical testing, manufacture, safety, effectiveness, approval, labeling, distribution, import, export, storage, record keeping, reporting, advertising and promotion of Valera's products. Product development and approval within this regulatory framework, if successful, will take many years and involve the expenditure of substantial resources. Violation of regulatory requirements at any stage may result in various adverse consequences, including FDA's delay in approving or refusal to approve a product. Violations of regulatory requirements also may result in enforcement actions including withdrawal of approval, labeling restrictions, seizure of products, fines, injunctions and civil or criminal penalties.

## Research, Development and Product Approval Process

The research, development and approval process in the United States is intensive and rigorous, and generally takes many years. The typical process required by the FDA before a therapeutic drug may be marketed in the United States includes:

pre-clinical laboratory and animal tests and analysis;

submission to the FDA of an application for an investigational new drug application, which must become effective before human clinical trials may commence;

preliminary human clinical studies to evaluate the drug and its manner of use;

adequate and well-controlled human clinical trials to establish whether the drug is safe and effective for its intended uses;

FDA review of whether the facility in which the drug is manufactured, processed, packed or held meets standards designed to assure the product s continued quality; and

submission and approval of an appropriate product application to the FDA, and approval of the application by the FDA. During pre-clinical testing, studies are performed with respect to the chemical and physical properties of candidate formulations. Biological testing is typically done in animal models to demonstrate the activity of the compound against the targeted disease or condition and to assess the apparent effects of the new product candidate on various organ systems, as well as its relative therapeutic effectiveness and safety. An investigational new drug application must be submitted to the FDA and become effective before studies in humans may commence.

In the United States, clinical trial programs in humans generally follow a three-phase process:

Phase I studies are typically conducted in small numbers of healthy volunteers or, on occasion, in patients afflicted with the target disease, to determine the metabolic and pharmacological action of the product candidate in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

Phase II studies are generally conducted in larger groups of patients having the target disease or condition in order to validate the clinical endpoint and to obtain preliminary data on both the effectiveness of the product candidate and optimal dosage. This phase also helps determine further the safety profile of the product candidate.

Phase III large-scale clinical trials are generally conducted in hundreds of patients having the target disease or condition to provide sufficient data for the statistical proof of effectiveness and safety of the product candidate.

In the case of products for cancer and certain other life-threatening diseases, however, the initial Phase I testing may be done in patients with the disease rather than in healthy volunteers. Because these patients are already afflicted with the target disease or condition, it is possible that such studies will provide results traditionally obtained in Phase II studies. These studies are often referred to as Phase I/II studies. Even if patients are used in initial human testing in a Phase I/II study, the sponsor is still responsible for obtaining all the data usually obtained in both Phase I and Phase II studies.

United States law requires that studies conducted to support approval for product marketing be adequate and well controlled. In general, this means that either a placebo or a product already approved for the treatment of the disease or condition under study must be used as a reference control. Studies must also be conducted in compliance with the FDA s good clinical practice regulations.

The clinical trial process can take up to ten years or more to complete, and the data may not be collected in compliance with good clinical practice regulations, demonstrate that the product is safe or effective, or be sufficient to support FDA approval of the product candidate. The FDA may place clinical trials on hold at any point in this process if, among other reasons, it concludes that clinical subjects are being exposed to an unacceptable health risk. Trials may also be terminated by institutional review boards, which must review and

approve all research involving human subjects. Side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing authorization. Similarly, adverse events that are reported after marketing authorization can result in additional limitations being placed on a product s use and, potentially, withdrawal of the product from the market. Any adverse event, either before or after marketing authorization, can result in liability claims against us.

During the course of, and following the completion of clinical trials, the data are analyzed to determine whether the trials successfully demonstrated safety and effectiveness and whether a product approval application may be submitted. In the United States, if the product is regulated as a drug, a new drug application must be submitted and approved before commercial marketing may begin. The FDA Center for Drug Evaluation and Research, known as CDER, has responsibility for the review and approval of drugs. The new drug application must include a substantial amount of data and other information concerning the safety and effectiveness of the compound from laboratory, animal and clinical testing, as well as data and information on manufacturing, product stability and proposed product labeling.

Each domestic and foreign biopharmaceutical manufacturing establishment, including any contract manufacturers Valera may decide to use, must be listed in the new drug application and must be registered with the FDA. The application will not be approved until the FDA conducts a manufacturing inspection, approves the applicable manufacturing process for the drug product and determines that the facility is in compliance with the FDA s current good manufacturing practice requirements. If the manufacturing facilities and processes fail to pass the FDA inspection, Valera will not receive approval to market these products.

Under the Prescription Drug User Fee Act, the FDA receives fees for reviewing a new drug application and supplements thereto, as well as annual fees for both commercial manufacturing establishments and approved products. These fees can be significant. The new drug application review fee alone can exceed \$0.9 million, although certain deferrals, waivers and reductions may be available.

Under applicable laws and FDA regulations, each new drug application submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If deemed complete, the FDA will file the new drug application, thereby triggering substantive review of the application. The FDA can refuse to file any new drug application that it deems incomplete or not properly reviewable. If the FDA refuses to file an application, the FDA will retain 25% percent of the user fee as a penalty. The FDA has established performance goals for the review of new drug applications six months for priority applications and ten months for regular applications. However, the FDA is not legally required to complete its review within these periods and these performance goals may change over time. Moreover, the outcome of the review, even if generally favorable, typically is not an actual approval but an action letter that describes additional work that must be done before the application can be approved. The FDA s review of an application may involve review and recommendations by an independent FDA advisory committee. Even if the FDA approves a product, it may limit the approved therapeutic uses for the product labeling, require that warning statements be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval or otherwise limit the scope of any approval.

Significant legal and regulatory requirements also apply after FDA approval to market under a new drug application. These include, among other things, requirements related to adverse events and other reporting, product advertising and promotion and ongoing adherence to current good manufacturing practices, as well as the need to submit appropriate new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. The FDA also enforces the requirements of the Prescription Drug Marketing Act, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

Overall research, development and approval times depend on a number of factors, including the period of review at the FDA, the number of questions posed by the FDA during review, how long it takes to respond to the

FDA questions, the severity of life-threatening nature of the disease in question, the availability of alternative treatments, the availability of clinical investigators and eligible patients, the rate of enrollment of patients in clinical trials and the risks and benefits demonstrated in the clinical trials.

## Drugs for Serious or Life-threatening Illnesses

The Federal Food, Drug and Cosmetic Act and FDA regulations provide certain mechanisms for the accelerated Fast Track approval of products intended to treat serious or life-threatening illnesses which have been studied for safety and effectiveness and which demonstrate the potential to address unmet medical needs. The procedures permit early consultation and commitment from the FDA regarding the pre-clinical and clinical studies necessary to gain marketing approval. Provisions of this regulatory framework also permit, in certain cases, new drug applications to be approved on the basis of valid surrogate markers of product effectiveness, thus accelerating the normal approval process. Valera has not applied for fast track status for any of Valera s current product candidates. However, certain product candidates employing Valera s Hydron Technology might qualify for this accelerated regulatory procedure. However, the FDA may not agree, and even if the FDA agrees that these products qualify for accelerated approval procedures, the FDA may deny approval of Valera s drugs or may require that additional studies be required before approval. The FDA may also require Valera to perform post-approval, or Phase IV, studies as a condition of such early approval. In addition, the FDA may impose restrictions on distribution and promotion in connection with any accelerated approval and may withdraw approval if post-approval studies do not confirm the intended clinical benefit or safety of the product candidates.

## Other United States Regulatory Requirements

In the United States, the research, manufacturing, distribution, sale and promotion of drugs may also be subject to regulation by various federal, state and local authorities including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), the United States Department of Health and Human Services and state and local governments. For example, sales, marketing and scientific and educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, and False Claims Act and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Moreover, Valera is now, and may become, subject to additional federal state and local laws, regulations and policies relating to safe working conditions, laboratory practices, and experimental use of animals, and the use, storage, handling, transportation and disposal of human tissue, waste and hazardous substances, including radioactive and toxic materials and infectious disease agents used in conjunction with Valera s research work.

## European Union Regulatory Requirements

Valera s ability to market its products outside the United States will be contingent upon receiving marketing authorizations from the appropriate regulatory authorities and compliance with applicable post-approval regulatory requirements. Although the specific requirements and restrictions vary from country to country, as a general matter, foreign regulatory systems include risks similar to those associated with FDA regulation, described above.

Under the European Union regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure. Under the centralized procedure, a single application to the European Medicines Agency, known as the EMEA, leads to an approval granted by the European Commission which permits the marketing of the product throughout the European Union. Valera assumes that the centralized

procedure will apply to Valera s products that are developed by means of a biotechnology process. The decentralized procedure provides for mutual recognition of nationally approved decisions and is used for products that do not qualify under the centralized procedure. Under the decentralized procedure, the holders of a national marketing authorization may submit further applications to the competent authorities of the remaining member states, which will then be requested to recognize the original authorization based upon an assessment report prepared by the original authorizing competent authority. The recognition process should take no longer than 90 days, but if one member state made an objection, which under the legislation can only be based on a possible risk to human health, Valera has the option to withdraw the application from that country or take the application to arbitration by the Committee for Proprietary Medicinal Products, known as CPMP, of the EMEA. If a referral for arbitration is made, the procedure is suspended, and in the intervening time, the only European Union countries are ready to recognize the product. The opinion of the CPMP, which is binding, could support or reject the objection or alternatively could reach a compromise position acceptable to all European Union countries concerned. Arbitration can be avoided if the application is withdrawn in the objecting country, but once the application has been referred to arbitration, it cannot be withdrawn. The arbitration procedure may take an additional year before a final decision is reached and may require the delivery of additional data.

As with FDA approval, Valera may not be able to secure regulatory approvals in certain European countries in a timely manner, if at all. Additionally, as in the United States, post-approval regulatory requirements, such as those regarding product manufacturers, marketing or distribution, would apply to any product that is approved in Europe, and failure to comply with such obligations could have a material adverse effect on Valera s ability to successfully commercialize any product.

There has recently been introduced in Europe new legislation designed to harmonize the regulation of clinical trials across the European Union, and that legislation is currently being implemented on a country-by-country basis. In addition, new proposals are under advanced consideration which, if brought into law, will effect substantial and material changes in the regulation of medicinal products in Europe. Accordingly, in seeking approval for Valera s products in Europe Valera faces a marked degree of chance and uncertainty both in the regulation of clinical trials and in respect of marketing authorizations.

Valera received regulatory approval to commercialize Vantas in Denmark in November 2005. In July 2006, Valera submitted an application for regulatory approval for Vantas in Germany, Ireland, Italy, Spain and the United Kingdom. Valera has completed the primary stage of the Mutual Recognition Procedure (MRP) process which concluded with a non-approvable status and referral to the Co-ordination Group for Mutual Recognition and Decentralized Procedure-Human, CMD(h). The CMD(h) arbitration failed to reach a consensus on approval and the procedure has been further referred to the Committee for Medicinal Products for Human Use (CHMP) at the European Agency for the Evaluation of Medicinal Products (EMEA). This final CHMP arbitration process will include all twenty-seven countries in the European Union where a majority rule will apply.

## Other Foreign Regulatory Requirements

Valera and its collaborative partners are subject to widely varying foreign regulations, which may be quite different from those of the FDA, governing clinical trials, product registration and approval and pharmaceutical sales. Whether or not FDA approval has been obtained, Valera must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in these countries. In certain countries, regulatory authorities also establish pricing and reimbursement criteria. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. In addition, under current United States law, there are significant restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

## Employees

As of December 31, 2006, Valera had 101 full-time employees, consisting of 37 individuals in sales and marketing, 20 individuals in manufacturing and distribution, 14 individuals in quality assurance and quality control, 16 individuals in research and development, and 14 individuals in management and administration. From time to time, Valera also employs independent contractors or consultants to support its clinical and regulatory efforts. None of Valera s employees are represented by a collective bargaining unit and Valera has never experienced a work stoppage. Valera believes that its relations with its employees are good.

## **Available Information**

Valera files annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any document Valera files with the SEC at the SEC s public reference room at 100 F Street, NE, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for information on the public reference room. The SEC maintains an internet site that contains annual, quarterly and current reports, proxy and information statements and other information that issuers (including Valera) file electronically with the SEC. Valera s electronic SEC filings are available to the public at the SEC s Internet site, *www.sec.gov*.

Valera s Internet site is *www.valerapharma.com*. You can access Valera s Investor Relations webpage through Valera s Internet site, *www.valerapharma.com*, by clicking on the Corporate Information link to the heading Investors. You can also access Valera s Investor Relations webpage directly at *www.valerapharma.com/investors.asp*. Valera makes available free of charge, on or through its Investor Relations webpage, its proxy statements, Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to the Securities Exchange Act of 1934, as amended (the Exchange Act ), as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. Valera also makes available, through Valera Investor Relations webpage, via a link to the SEC s Internet site, statements of beneficial ownership of Valera s equity securities filed by its directors, officers, 10% or greater shareholders and others under Section 16 of the Exchange Act.

Valera has a webpage with its Corporate Code of Business Conduct and Ethics and certain Corporate Governance information. You can access this information on Valera's webpage through Valera's Internet site, *www.valerapharma.com*, by clicking on the Corporate Information link to the heading Investors. Valera will post any amendments to the Code of Business Conduct and Ethics, and any waivers that are required to be disclosed by the rules of either the SEC or The NASDAQ Global Market, on Valera's Internet site.

You can request a copy of these documents, excluding exhibits, at no cost, by contacting Investor Relations, 7 Clarke Drive, Cranbury, NJ 08512 or (609-235-3000). The information on Valera s Internet site is not incorporated by reference into this report.

#### Properties

Valera maintains its headquarters and manufacturing facility in Cranbury, New Jersey in two leased facilities consisting of a total of 51,046 square feet. The following table sets forth more information regarding Valera s facilities.

Address	Square Feet	Function	Lease Expiration	
7 Clarke Drive Cranbury, NJ	21,274	Research and Development; Administration	2015	
8 Clarke Drive Cranbury, NJ	29,772	Manufacturing	2015	
Valera s manufacturing facility is subject to periodic inspections by the FDA and other federal and state regulatory agencies and is subject to				
cGMP regulations. Despite the relative complexity and length of Valera s manufacturing process, Valera believes that its existing manufacturing				
facilities are capable of producing commercial quantities of its implants. In order to achieve cost-effective production, Valera has developed				
proprietary equipment and scalable commercial manufacturing methods that it uses in its production line.				

In May 2005, Valera began a construction project at its headquarters to increase the size of its manufacturing facility. As of January 2007, Valera has completed this project and the new manufacturing space is being prepared for use. Valera believes that its current manufacturing facilities, as supplemented by the recently completed manufacturing space will provide sufficient capacity to meet its current needs and support the introduction of new products over the next several years.

## Legal Proceedings

Valera is not subject to any pending or, to Valera sknowledge, threatened material litigation.

## MANAGEMENT S DISCUSSION AND ANALYSIS OF

#### FINANCIAL CONDITION AND RESULTS OF OPERATIONS OF VALERA

You should read the following discussion and analysis of Valera's financial condition and results of operations in conjunction with Valera's consolidated financial statements and the notes to those consolidated financial statements beginning on page 184 of this joint proxy statement/prospectus. Certain information contained in this discussion and analysis and presented elsewhere in this document includes forward-looking statements that involve risk and uncertainties. In evaluating these statements, you should note that if the merger agreement and the merger are approved, it is possible that certain matters discussed below which concern future periods will be affected in ways that may not be currently known to Valera. You should specifically consider the various risk factors set forth under's fork Factors' in Valera's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and those that are set forth under's forward-looking statements.

#### Overview

Valera is a specialty pharmaceutical company concentrating on the development, acquisition and commercialization of products for the treatment of urological and endocrine conditions, diseases and disorders, including products that utilize Valera's proprietary drug delivery technology. Valera's first product, Vantas, was approved by the FDA in October 2004. Vantas is a 12-month hydrogel implant based on Valera's patented Hydron Technology indicated for the palliative treatment of advanced prostate cancer that delivers histrelin, a luteinizing hormone-releasing hormone agonist, or LHRH agonist. Valera began marketing Vantas in the United States in November 2004 utilizing its own sales force. In December 2006, Valera entered into a co-promotion agreement with Indevus and in January 2007, pursuant to the co-promotion arrangement, Valera began to jointly promote Vantas with Indevus with an aggregate sales force of approximately 105 individuals that are currently calling on urologists in the United States that account for the majority of LHRH agonist product sales. Total U.S. sales of LHRH agonist products being the three and four-month injection formulations. Valera believes that total U.S. sales of LHRH agonist products declined by 5% in 2006, primarily as a result of lower prices due to changes in Medicare reimbursement rates. Valera expects future reimbursement levels to continue to decline, which will have an adverse effect on Valera's net product sales. Valera believes that Vantas has a competitive advantage over other LHRH agonist products because it delivers an even, controlled dose of a LHRH agonist over a 12-month period, and is the only product indicated for the palliative treatment of advanced prostate cancer that delivers histrelin, the most potent LHRH agonist available.

Valera plans to seek marketing approvals for Vantas in various countries throughout the world. In November 2005, Valera announced that it received approval to market Vantas in Denmark and in July 2006, Valera submitted an application for regulatory approval in Germany, Ireland, Italy, Spain and the United Kingdom. In July 2006, Valera announced a partnership with Spepharm to market Vantas in Denmark and throughout Europe. Valera has completed the primary stage of the Mutual Recognition Procedure (MRP) process which concluded with a non-approvable status and referral to the Co-ordination Group for Mutual Recognition and Decentralized Procedure-Human, CMD(h). The CMD(h) arbitration failed to reach a consensus on approval and the procedure has been further referred to the Committee for Medicinal Products for Human Use (CHMP) at the European Agency for the Evaluation of Medicinal Products (EMEA). This final CHMP arbitration process will include all twenty-seven countries in the European Union where a majority rule will apply. In March 2006, Valera announced that Paladin Labs, Valera s marketing partner in Canada, received approval from Health Canada to market Valera s Vantas product in Canada. Subsequently, Paladin Labs submitted an application for reimbursement to the Canadian Common Drug Review (CDR) and the Conseil du Médicament du Québec and this documentation is under review. As of December 31, 2006, in conjunction with BioPro Pharmaceutical Inc., Valera s marketing partner for most countries in Asia, Vantas was submitted for regulatory approval in Thailand, Singapore, Malaysia, Taiwan, Korea Hong Kong and China.

In March 2006, Valera acquired Valstar, a product for the treatment of bladder cancer that is no longer responsive to conventional treatment such as surgery or topical drug application. Valera expects to launch this product in the second or third quarter of 2007.

In June 2006, Valera submitted a New Drug Application (NDA) to the United States Food and Drug Administration for Supprelin-LA, a twelve-month implant for the treatment of central precocious puberty. In September 2006, Valera announced that the FDA had accepted the submission of its NDA for Supprelin-LA. Accordingly, under the Prescription Drug User Fee Act (PDUFA) guidelines, the FDA is expected to complete its review and act upon this NDA submission by the PDUFA required date of May 3, 2007. Valera also announced that its Supprelin-LA manufacturing facilities in Cranbury, New Jersey successfully passed a recent FDA pre-approval inspection. In November 2005, the FDA granted Supprelin-LA orphan drug designation which provides seven years marketing exclusivity from date of marketing approval as well as certain economic benefits and tax credits.

In addition to Supprelin-LA, Valstar and Vantas, Valera is developing a pipeline of proprietary product candidates for indications that include acromegaly, opioid addiction, interstitial cystitis and nocturnal enuresis. Several of Valera's product candidates also utilize Valera's Hydron Technology delivery system. Valera intends to leverage its existing specialized sales force to market certain of its product candidates, if approved, since the indications of these product candidates are treated by many of the same physicians Valera is calling on for Vantas.

In May 2006, Valera submitted an Investigational New Drug Application (IND) for its VP004 (naltrexone implant) to the FDA and that filing has been accepted by the agency. In November 2006, Valera finalized all administrative arrangements with Johns Hopkins necessary to begin clinical studies for VP004. The three month Phase I/II study will involve an open label study of the naltrexone implant in approximately a dozen health volunteers with a history of opioid abuse. A primary objective of the study is to investigate several dosing regimens for the extent of opiate blockade following morphine challenges. The lead investigator is the pioneering addiction researcher and renowned authority on naltrexone, Donald Jasinski, M.D., Professor of Medicine, Chief Center for Chemical Dependence, Johns Hopkins Bayview Medical Center. The study began in November 2006 and data related to the study is expected to be provided to the FDA for review in the third quarter of 2007. Valera expects to commence a Phase III clinical trial in the first half of 2008.

On November 8, 2006, Valera announced that it completed proof-of-concept studies on a flexible, biodegradable polymer-based ureteral stent. Ureteral stents are plastic tubes inserted into the ureter to allow urine to drain from the kidney to the bladder when the flow of urine may be obstructed due to a number of conditions, including kidney stones and inflammation. Current available ureteral stents require physician intervention for removal from the body. A biodegradable ureteral stent could be naturally voided by the body, a potentially important advantage over existing stents. In February 2007, Valera announced that it had initiated a porcine model study to establish safety and effectiveness necessary to support the submission of a 510k device application for the polymer-based flexible biodegradable ureteral stent. This study will involve 30 pigs with a primary end point being the dissolution and natural excretion of the stent within several weeks. Depending on the outcome of the study, the 510k submission could occur by the end of 2007.

In December 2006, Valera entered into a merger agreement with Indevus Pharmaceuticals pursuant to which Indevus will acquire Valera in a tax-free stock-for-stock merger transaction. Pursuant to the Merger Agreement, upon the closing of the merger, each outstanding share of Valera's common stock (other than shares held by Valera or Indevus or any stockholders who properly exercise appraisal rights under Delaware law), will automatically be converted into the right to receive a number of shares of Indevus common stock equal to \$7.75 divided by the volume weighted average of the closing prices of Indevus common stock during the 25 trading days ending on the fifth trading day prior to the date of Valera's stockholders' meeting to consider the merger, or the Indevus Common Stock Value. The exchange ratio is subject to a collar such that if the Indevus Common Stock Value falls outside of the collar the exchange ratio will become fixed. If the Indevus Common

Stock Value is greater than \$8.05, then the exchange ratio will be 0.9626, and if the Indevus Common Stock Value is less than \$6.59, then the exchange ratio will be 1.1766. Cash will be paid in lieu of fractional shares. See the sections entitled The Merger Material United States Federal Income Tax Consequences and The Merger Agreement Merger Consideration.

In addition, each share of Valera s common stock will be converted into three contingent stock rights, or CSRs, relating to three of Valera s product candidates. One CSR will be convertible into \$1.00 of Indevus common stock upon FDA approval of Supprelin-LA, provided sufficient quantities of Supprelin-LA are then available, one CSR will be convertible into \$1.00 of Indevus common stock upon FDA approval of Valera s biodegradable ureteral stent and one CSR will be convertible into \$1.50 of Indevus common stock upon FDA approval of Valera s octreotide implant. The amount of Indevus common stock into which the CSRs will convert will be determined by a formula based on the average stock price of Indevus prior to achievement of the applicable milestones. The CSRs will convert into Indevus common stock only if the applicable milestones are achieved within three years of the closing of the merger in the case of Supprelin-LA and within five years of the closing of the merger in the case of Valera s biodegradable ureteral stent and octreotide implant. See the section entitled The Merger Agreement Merger Consideration.

In connection with the merger transaction, certain affiliated funds of Sanders Morris Harris, Valera's largest stockholder, and one other large stockholder of Valera, entered into voting agreements with Indevus in which they have agreed to vote shares representing approximately 41% of the outstanding shares of Valera's common stock in favor of the merger. The merger has been approved by Valera's board of directors, as well as Indevus' board of directors. Valera anticipates that the merger will close at the end of April 2007. The merger is subject to certain customary closing conditions, including the approval of Valera's stockholders and the approval of Indevus's stockholders. See the section entitled The Merger Agreement Conditions to Completion of the Merger.

James C. Gale, chairman of Valera's board of directors and chief investment officer of the Corporate Opportunities Funds and Life Sciences Opportunities Fund, affiliates of Sanders Morris Harris, is expected to join the Indevus board of directors. Sanders Morris Harris is currently Valera's largest shareholder. Additionally, Dr. David Tierney, Valera's President and Chief Executive Officer, will provide consulting services during a transition period after the completion of the merger transaction. Valera's facility in Cranbury, New Jersey, which contains significant manufacturing operations and research and development capabilities, will be maintained and become an integral part of Indevus operations.

If the merger is not completed for any reason, Valera s ongoing business may be adversely affected and will be subject to a number of risks, including:

Valera might have to pay Indevus a termination fee of \$5.0 million, or Valera might be required to reimburse Indevus for up to \$3.0 million of expenses relating to the merger, such as legal, accounting, financial advisory and printing fees;

the inability to pursue other beneficial opportunities as a result of the focus of Valera s management on the merger, without realizing any of the anticipated benefits of completing the merger;

the market price of Valera s common stock might decline to the extent that the current market price reflects a market assumption that the merger will be completed; and

Valera s unreimbursed costs incurred related to the merger, such as legal, accounting, financial advisory and printing fees, must be paid even if the merger is not completed.

If the merger agreement is terminated and Valera s board of directors seeks another merger or business combination, Valera s stockholders cannot be certain that Valera will be able to find a party willing to pay an equivalent or more attractive price than the price Indevus has agreed to pay in the merger.

Valera will incur substantial expenses related to the merger whether or not the merger is completed. These expenses include legal, accounting, financial advisory and printing fees. As of December 31, 2006, Valera has

incurred approximately \$0.8 million related to the merger transaction. Moreover, in the event the merger agreement is terminated, Valera may, under certain circumstances, be required to pay Indevus a \$5.0 million termination fee or reimburse Indevus out-of-pocket expenses of up to \$3.0 million. Also, should the merger agreement be terminated due to a willful breach of the merger agreement by Valera, Valera could owe significant damages to Indevus.

Separately, in December 2006, Valera entered into a co-promotion agreement with Indevus pursuant to which Indevus sales force will co-promote Vantas in the United States. Under the terms of the agreement, Valera will be required to make royalty payments to Indevus of 13.5% on sales of Vantas up to a specified unit level, which will increase to 30% for sales above the specified level. Indevus will also receive royalties of 35% for sales of Vantas to specified specialty pharmacy accounts. Additionally, the co-promotion agreement provides Valera with the option to elect to enter into negotiations with Indevus to grant Indevus a co-exclusive right to co-promote Supprelin-LA. The co-promotion began in January 2007.

Valera expects to continue to spend significant amounts on the development and commercialization of its product candidates. While Valera will be focusing on the clinical development of its later stage product candidates in the near term, Valera expects to increase its spending on earlier stage clinical candidates as well. Valera also aims to build its urological and endocrine product portfolio and opportunistically acquire or in-license later-stage urological and endocrine product that are currently on the market or require minimal development expenditures, or have some patent protection or potential for market exclusivity or product differentiation. Further, Valera intends to collaborate with major and specialty pharmaceutical companies to develop and commercialize products that are outside of its core urology and endocrinology focus. Accordingly, Valera will need to generate significant revenues or else need additional financing to fund these efforts.

Drug development in the United States and most countries throughout the world is a multi-stage process controlled by the FDA and similar regulatory authorities in foreign countries. In the United States, the FDA approval process for a new drug involves completion of pre-clinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an investigational new drug application, which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase I, II and III. The most significant expenses associated with clinical development are the Phase III clinical trials as they tend to be the longest and largest studies conducted during the drug development stage. In responding to a new drug application, the FDA may refuse to accept the application, or if accepted for filing, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. In order to commence clinical trials or marketing of a product outside the United States, Valera must obtain approval of the applicable foreign regulatory authorities. Although governed by the laws and regulations of the applicable country, clinical trials conducted outside the United States typically are administered in a similar three-phase sequential process.

The successful development of Valera s product candidates is highly uncertain. Valera cannot reasonably estimate or know the nature, timing and estimated expenses of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from any of its product candidates due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

the scope, rate of progress and expense of Valera s clinical trials and other research and development activities;

future clinical trial results;

the expense of clinical trials for additional indications;

the terms and timing of any collaborative, licensing and other arrangements that Valera may establish;

the expense and timing of regulatory approvals;

the expense of establishing clinical and commercial supplies of Valera s product candidates and any products that Valera may develop;

the effect of competing technological and market developments; and

the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights. Research and development expenses consist primarily of costs incurred for clinical trials and manufacturing development costs related to Valera s clinical product candidates, personnel and related costs related to Valera s research and product development activities and outside professional fees related to clinical development and regulatory matters. Valera does not disclose estimated research and development costs for product candidates that are not yet in Phase III clinical trials.

## **Basis of Presentation**

## **Product Sales and Costs**

Valera generates revenues from sales of Vantas, its first commercialized product. Valera began commercial sales of Vantas in the United States in November 2004. Prior to June 2006, all sales of Vantas were in the United States. In June 2006, Valera made its first international shipment of Vantas to Paladin Labs in Canada. In the United States, Valera distributes Vantas directly to physicians, or through Besse Medical Distribution Company, or Besse Medical, which is a subsidiary of AmerisourceBergen Corporation.

Valera s business is affected by physician utilization, pricing pressure from Valera s competition and Medicare or third party reimbursement, as well as other factors which may cause variances in Valera s revenue. Valera s sales of Vantas from launch in November 2004 through June 30, 2005 were supported, in part, by favorable Medicare reimbursement rates, which decreased beginning in the third quarter of 2005. Valera s initial favorable reimbursement rates were due to the fact that Vantas was a new product that did not yet have an established average selling price, or ASP, in connection with Medicare reimbursement. As a result, Vantas was reimbursed at wholesale acquisition price, which is typically higher than ASP. Vantas received an established ASP effective July 2005, which resulted in lower reimbursement rates and a corresponding lower sales price to Valera s customers. Valera s historical quarterly net average selling prices to its customers are:

For the three months ended:	Selling Pr
December 31, 2004	\$ 2,5
March 31, 2005	\$ 2,6
June 30, 2005	\$ 2,5
September 30, 2005	\$ 2,0
December 31, 2005	\$ 1,8
March 31, 2006	\$ 1,6
June 30, 2006	\$ 1,5
September 30, 2006	\$ 1,4
December 31, 2006	\$ 1,3

Valera expects future Medicare reimbursement levels to continue to decline for Vantas, which will have an adverse effect on Valera's net product sales. Reimbursement levels are currently set by the twenty-three Medicare carriers in the United States which, in the aggregate, cover all fifty states. Certain Medicare carriers have a policy which sets the reimbursement rate for Vantas based on Valera's ASP. Other Medicare carriers have a policy that applies the least costly alternative, or LCA, methodology to Vantas. LCA is a payment methodology

Net Average

that allows Medicare carriers to pay the same reimbursement for drugs that have been determined by Medicare to be medically equivalent. Vantas is currently the least costly alternative in the class of LHRH drugs. Further, certain Medicare carriers have a policy which segregates twelve-month products from all other dosages, including one, three, four and six month injectable products, and reimburses at different rates for these two groups of products, sometimes referred to as a split policy. Finally, there are certain Medicare carriers which state they have a policy which reimburses on an ASP or LCA methodology, but which Valera believes make payments based upon a split policy.

Valera is devoting internal and external resources to determine the impact and fairness of these various policies. In the states where certain Medicare carriers have adopted a split policy, in writing or in practice, Valera is at an economic disadvantage to the injectable products which are reimbursed at higher annual rates. Valera is challenging the basis for these reimbursement policies with the Medicare carriers. Valera will deploy its sales resources in markets where it can sell its products on an even par with the other products in the class. Nevertheless, Valera expects its net product sales to continue to decline in the foreseeable future as a result of the declining reimbursement rates for Vantas.

Valera is also pursuing a sales strategy in which it will attempt to sell a greater percentage of Vantas to non-Medicare customers. Non-Medicare customers typically pay a greater amount for Vantas than Medicare customers. Thus, selling a greater percentage of Vantas to non-Medicare customers may alleviate the downward pressure on Valera s net average selling price from the Medicare customers.

Valera s cost of product sales are all related to the production of Vantas and represent the cost of materials, overhead associated with the manufacture of Vantas, direct labor, distribution charges and royalties. Prior to approval of Vantas in October 2004, Valera expensed all of its manufacturing costs as research and development.

## **Research and Development Expenses**

Valera s research and development expenses consist of costs incurred for company-sponsored and collaborative research and development activities. These expenses consist primarily of direct and research-related allocated overhead expenses such as facilities costs, salaries and benefits and material supply costs. Valera does not track or report its research and development expenses on a project basis as Valera does not have the internal resources or systems to do so.

## Selling and Marketing Expenses

Selling and marketing expenses consist primarily of sales and marketing personnel compensation, sales force incentive compensation, travel, tradeshows, promotional materials and programs, advertising and healthcare provider education materials and events.

#### General and Administrative Expenses

Valera s general and administrative expenses consist primarily of personnel expenses for accounting, human resources, outside consulting, information technology and corporate administration functions. Other costs include administrative facility costs, regulatory fees, and professional fees for legal and accounting services.

## Amortization of Intangible Assets

The amortization of intangible assets relates to Valera's acquisition of the product rights associated with the product known as Valstar (valrubicin) in the United States and Valtaxin in Canada. Valera is amortizing the product rights over 5 years using the straight-line method.

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

Valera's discussion and analysis of its financial condition and results of operations are based on Valera's financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires Valera to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenue and expenses during the reporting periods. Valera continually evaluates its judgments, estimates and assumptions. Valera bases its estimates on the terms of underlying agreements, the expected course of development, historical experience and other factors that Valera believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources.

Actual results may differ from these estimates under different assumptions or conditions. The list below is not intended to be a comprehensive list of all of Valera s accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. There are also areas in which the judgment of Valera s management in selecting an available alternative would not produce a materially different result.

## **Revenue Recognition**

Valera s revenue recognition policies are in accordance with Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition in Financial Statements* (SAB 104), and SFAS No. 48, *Revenue Recognition When Right of Return Exists* (SFAS 48), which provides guidance on revenue recognition in financial statements, and is based on the interpretations and practices developed by the Securities and Exchange Commission. SFAS 48 and SAB 104 require that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the seller s price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured. Determination of criteria (3) and (4) are based on management s judgments regarding the fixed nature of the fee charged for services rendered and products delivered and the collectibility of those fees. Should changes in conditions cause management to determine that these criteria are not met for certain future transactions, revenue recognition for those transactions will be delayed and Valera s revenue could be adversely affected.

Allowances have been recorded for any potential returns or adjustments in accordance with Valera policies. Valera historically has recorded allowances based upon a percentage of gross sales. Valera distributes its product directly to physicians or through its distributor, Besse Medical. The majority of Valera s sales are made directly to physicians by Valera s product specialists. Valera believes that physicians typically order product on an as needed basis, and, therefore, typically maintain inventory of Valera s product only to cover their immediate and short-term future requirements. In addition, Valera s product specialists routinely confirm product utilization and inventory levels, if any, as part of their normal sales calls with physicians. Valera continues to monitor its distribution channels in order to assess the adequacy of its allowances. Valera does not believe that it is reasonably likely that a material change will occur in the allowance as of December 31, 2006.

#### Pre-clinical Study and Clinical Trial Expenses

Research and development expenditures are charged to operations as incurred. Valera's expenses related to clinical trials are based on actual and estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on Valera's behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses related to clinical trials generally are accrued based on contracted amounts applied to the level of patient enrollment and activity

according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, Valera modifies its estimates accordingly on a prospective basis.

## Stock-Based Compensation

Valera adopted SFAS No. 123(R), *Shared-Based Payment* on January 1, 2006. SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. Under SFAS 123(R), the options Valera granted in prior years as a non-public company (prior to the initial filing of Valera s Registration Statement in March 2005) that were valued using the minimum value method, will not be expensed in 2006 or future periods. Options granted as a non-public company and accounted for using the intrinsic value method (cheap stock), will continue to be expensed over the vesting period. Valera adopted the prospective transition method for these options. Options granted as a public company are expensed under the modified prospective method.

SFAS No. 123(R) does not change the accounting guidance for how Valera accounts for options issued to non-employees. Valera accounts for options issued to non-employees under SFAS No. 123 and EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.* As such, the value of such options is periodically re-measured and income or expense is recognized during their vesting terms.

#### **Results of Operations**

#### Comparison of the Years Ended December 31, 2006 and 2005

*Net Product Sales.* Valera s net product sales for the years ended December 31, 2006 and 2005 were approximately \$17.8 million and \$26.8 million, respectively. The 33% decrease in net product sales was primarily due to lower net average selling prices due to decreased Medicare reimbursement rates for Valera s Vantas product as well as increased competition around pricing in the class of LHRH drugs. For the year ended December 31, 2006, Valera sold 11,663 units of Vantas in the United States at a net average selling price of \$1,526 per unit as compared to 11,514 units at a net average selling price of \$2,327 for the year ended December 31, 2005. As a result of pre-launch shipments of Vantas for Canada, Valera sold 169 units of Vantas to Paladin Labs, Valera s marketing partner in Canada. Thus, worldwide unit sales of Vantas increased by 3%, or 318 units, for the year ended December 31, 2006, as compared to the year ended December 31, 2005.

Vantas is currently eligible for insurance reimbursement coverage. Sales of Vantas in the year ended December 31, 2005 were supported, in part, by favorable Medicare reimbursement rates, due to the fact Vantas was a new product that did not yet have an established average selling price, or ASP, and it was reimbursed at wholesale acquisition price, which is typically higher than ASP. Effective July 2005, Vantas received an established ASP, which resulted in a lower reimbursement rate.

Valera expects future Medicare reimbursement levels to continue to decline for Vantas, which will have an adverse effect on Valera's net product sales. Reimbursement levels are currently set by the twenty-three Medicare carriers in the United States which, in the aggregate, cover all fifty states. Certain Medicare carriers have a policy which sets the reimbursement rate for Vantas based on Valera's ASP. Other Medicare carriers have a policy that applies the least costly alternative, or LCA, methodology to Vantas. LCA is a payment methodology that allows Medicare carriers to pay the same reimbursement for drugs that have been determined by Medicare to be medically equivalent. Vantas is currently the least costly alternative in the class of LHRH drugs. Further, certain Medicare carriers have a policy which segregates twelve-month products from all other dosages, including one, three, four and six month injectable products, and reimburses at different rates for these two groups of products, or a split policy. Finally, there are some Medicare carriers which state they have a policy

which reimburses on an ASP or LCA methodology, but which Valera believes make payments based upon a split policy.

Valera is devoting internal and external resources to determine the impact and fairness of these various policies. In the states where certain Medicare carriers have adopted a split policy, in writing or in practice, Valera is at an economic disadvantage to the injectable products which are reimbursed at higher annual rates. Valera is challenging the basis for these reimbursement policies with the Medicare carriers. Valera will deploy its sales resources in markets where it can sell its products on an even par with the other products in the class.

Valera is also pursuing a sales strategy in which it will attempt to sell a greater percentage of Vantas to non-Medicare customers. Non-Medicare customers typically pay a greater amount for Vantas than Medicare customers. Thus, selling a greater percentage of Vantas to non-Medicare customers may alleviate the downward pressure on Valera s net average selling price from the Medicare customers. In addition, Valera continues to review a number of strategic options to broaden the penetration of Vantas into the LHRH market. In December 2006, Valera entered into a co-promotion agreement with Indevus under which Indevus sales force will co-promote Vantas in the United States. Terms of the agreement provide Indevus with royalties of 13.5% on sales of Vantas up to a specified unit level and increases to 30% above the specified level. For sales of Vantas to specified specialty pharmacy accounts, Indevus will receive royalties of 35%. The co-promotion began in January 2007.

*Licensing Revenue.* For the years ended December 31, 2006 and 2005, Valera recorded licensing revenues of approximately \$121,000 and \$34,000, respectively. In September 2006, Valera received \$100,000 from BioPro for licensing revenue related to the submission of Vantas for regulatory approval in Taiwan. This payment is in accordance with the exclusive license and distribution agreement with BioPro to sell Vantas in various countries in Asia. The remaining \$21,000 of licensing revenue during the year ended December 31, 2006 was from Hydron Technologies. The entire \$34,000 in licensing revenue during the year ended December 31, 2005 was from Hydron Technologies. Valera receives licensing revenue from Hydron Technologies for products marketed or sold by Hydron Technologies that utilize Valera s patented Hydron polymer technology.

*Cost of Product Sales*. Valera s cost of product sales for the years ended December 31, 2006 and 2005 was approximately \$5.1 million and \$6.0 million, respectively. Gross margins as a percentage of net product sales for the years ended December 31, 2006 and 2005 were 71% and 78%, respectively. The decrease in gross margin percentage was primarily due to a decrease in the net average selling prices which was slightly offset by an inventory reserve charge recorded in prior year. During the year ended December 31, 2005, a \$1.0 million inventory reserve was recorded for certain products that failed to meet Valera s quality control specifications. Lower expected net average selling prices as a result of decreased Medicare reimbursement rates for Valera s Vantas product as well as higher manufacturing overhead will have a negative impact on Valera s gross margins going forward. Valera expects the gross margin percentage to be in the mid sixty percent range in 2007.

*Research and Development Expense*. Valera's research and development expense for the years ended December 31, 2006 and 2005 was approximately \$7.6 million and \$5.9 million, respectively. The 28% increase was primarily due to expenses related to development of Valstar, Supprelin-LA, Octreotide, Naltrexone, and the ureteral stent. Valera's expenses related to clinical trials and research projects pursuant to contracts with research institutions and clinical research organizations represented 47% of Valera's total research and development expense for the year ended December 31, 2006 compared to 45% of Valera's research and development expense for the year ended December 31, 2005. Internal research and development expense was approximately 53% and 55% of Valera's total research and development expense for the years ended December 31, 2006 and 2005, respectively. Valera expects to continue to spend significant amounts, including clinical trial costs, on the development of its product candidates. In August 2006, the FDA requested an additional Phase I/II study for Valera's Octreotide implant which is expected to cost approximately \$0.9 million. Valera expects to commence a Phase III trial for the Octreotide implant in the second half of 2007. The Octreotide Phase III trial is expected to last approximately eighteen months and is expected to cost approximately \$6.0 million to \$7.0 million.

*Selling and Marketing Expense*. Valera s selling and marketing expense for the years ended December 31, 2006 and 2005 was approximately \$12.1 million and \$10.8 million, respectively. The 13% increase was primarily attributable to an increase in salaries of approximately \$0.5 million, stock based compensation expense of approximately \$0.1 million, employee benefits of approximately \$0.2 million, and travel of approximately \$0.3 million related to an increase in the number of employees dedicated to Valera s sales and marketing efforts. Valera increased its selling and marketing organization by six individuals on average from 2005 to 2006. Valera expects its selling and marketing expenses to increase in the future as a result of the co-promotion arrangement with Indevus Pharmaceuticals which commenced in January 2007. As a result of the co-promotion arrangement, 105 individuals from both companies are currently calling on urologists and promoting Vantas. The increased selling and marketing efforts will yield additional co-promotion marketing and material costs as well as co-promotion fees that will be due to Indevus Pharmaceuticals.

*General Administrative Expense*. Valera s general administrative expense for the years ended December 31, 2006 and 2005 was approximately \$8.2 million and \$5.5 million, respectively. The 48% increase was primarily due to an increase in non-cash stock based compensation expense of approximately \$1.0 million, \$0.5 million in directors and officer s liability insurance expense, \$0.2 million in rent, \$0.2 million in director fees, and \$0.8 million of professional fees related to the potential merger transaction with Indevus Pharmaceuticals.

*Amortization of Intangible Assets.* Valera s amortization expense for the year ended December 31, 2006 was approximately \$79,000. The amortization of intangible assets relates to product rights associated with the product known as Valstar (valrubicin) in the United States and Valtaxin in Canada, which Valera acquired in March of 2006. As such, Valera had no amortization expense for the year ended December 31, 2005.

*Net Interest Income*. Valera s net interest income was approximately \$941,000 and \$49,000 for the years ended December 31, 2006 and 2005, respectively. The increase was primarily due to the increased cash and investments balance resulting from the proceeds of the initial public offering of Valera s common stock in February 2006.

*Income Taxes.* Valera s income tax benefit for the year ended December 31, 2006 was approximately \$207,000. As a result of the loss of approximately \$14.1 million for the year ended December 31, 2006, as well as the previous net operating losses since Valera s inception, Valera did not record any federal provision for income taxes during the year ended December 31, 2006. Valera did record a provision of approximately \$21,000 during the period for state taxes subject to alternative minimum tax. The provision was offset by approximately \$35,000 of tax benefits recorded as a result of the finalizing and filing of Valera s 2005 federal and state tax returns. In addition, in 2006, the New Jersey Economic Development Authority approved the Company s application to sell New Jersey State income tax benefits under the New Jersey Technology Tax Transfer Program. During the fourth quarter of 2006, Valera recognized approximately \$193,000 from the sale of the State of New Jersey income tax benefits. The Technology Tax Transfer Program requires that Valera maintain certain employment levels in New Jersey and that the proceeds from the sale of the tax benefits be spent in New Jersey. Valera has incurred net operating losses since inception. However, in 2005 Valera generated taxable income as a result of certain temporary and permanent differences between book income and taxable income. As a result Valera recorded an alternative minimum tax provision of \$20,000 for federal purposes and \$55,000 for state taxes. Valera s deferred tax assets primarily consist of net operating loss carry forwards and research and development tax credits. Valera has recorded a valuation allowance for the full amount of Valera s deferred tax asset, as the realization of the deferred tax asset is uncertain.

## Comparison of the Years Ended December 31, 2005 and 2004

*Net Product Sales.* Valera s net product sales for the year ended December 31, 2005 were \$26.8 million, during which period Valera sold 11,514 units of Vantas at a net average selling price per unit of \$2,327. Valera s net product sales for the year ended December 31, 2004 were \$5.5 million during which period Valera sold 2,187

units of Vantas at a net average selling price per unit of \$2,520. The increase in net product sales of \$21.3 million, or 386%, was primarily due to the fact Valera launched Vantas, its only commercialized product, in November 2004 and as a result, Valera had only two months of sales in 2004.

Valera s net average selling price to its customers was \$2,604 for the six months ended June 30, 2005. The net average selling price declined to \$2,099 during the three months ended September 30, 2005 and further declined to \$1,801 per unit during the three months ended December 31, 2005.

In the second and third quarters of 2005, Valera experienced a disruption in its manufacturing of Vantas due to issues caused by Valera's supply of histrelin. This manufacturing disruption which occurred in May and June of 2005 limited the amount of finished product available for sale in the third quarter of 2005 to three lots, or approximately 2,400 units. The issue was resolved in June and Valera released approved finished product in August. Valera's third quarter sales of 1,747 units were less than its sales in the first and second quarters of 2005, in which Valera sold 2,925 units and 3,974 units, respectively. As a result of this decrease in sales, Valera had a net loss in the third quarter of 2005. Valera's production of Vantas in the fourth quarter of 2005 was sufficient to meet demand as well as to continue to build quantities of finished goods inventory.

*Licensing Revenue.* During the year ended December 31, 2005, Valera recorded \$34,000 in licensing revenue from Hydron Technologies under a licensing arrangement. In addition, in January 2005 Valera received \$300,000 from BioPro, Valera s distribution partner for certain countries in Asia. The BioPro payment is reflected as deferred revenue on Valera s December 31, 2005 balance sheet. Valera will recognize this payment ratably over a ten-year period once Vantas is approved in the licensed territory. In 2004, back fees of \$135,000 were paid, as an agreement with Hydron Technologies to terminate the cross licensing agreement could not be reached.

*Cost of Product Sales.* Valera s cost of product sales for the year ended December 31, 2005 was \$6.0 million resulting in a gross margin of 78%. In 2004, Valera s cost of product sales was \$0.6 million and the gross margin percentage was 89% due to higher selling prices and lower costs on a per unit level. The 2004 gross margin percentage includes the benefit of the sale of units that were partially manufactured prior to FDA approval and, as such, were previously partially expensed. As discussed previously, during the second quarter of 2005, due to an issue regarding Valera s supply of histrelin, the active ingredient in Vantas, several lots of Vantas that Valera produced did not meet Valera s quality control specifications. Specifically, Valera acquired a supply of histrelin in January 2005 from Valera s single-source supplier and Valera used that histrelin during February, March and April in the production of Vantas. In May and June of 2005, Valera discovered that the histrelin had lower than normal solubility. This caused the lots made with that histrelin to fail to meet Valera s quality control specifications and, as a result, those lots were not available for sale. This resulted in the write-off of five lots of Vantas in May and June of 2005 which had an unfavorable impact of approximately \$1 million. The issue was resolved in June and Valera released approved finished product in August. Valera expects the gross margin percentage to decrease in future periods as Valera expects its net average selling price of Vantas to decrease as a result of declining reimbursement rates.

Valera s cost of product sales calculation includes royalty expense of \$1.3 million and \$0.3 million for the years ended December 31, 2005 and 2004, respectively. Freight and distribution expense is also included in the cost of product sales for all periods presented.

*Research and Development Expense.* Valera s research and development expense for the years ended December 31, 2005 and 2004 was \$5.9 million and \$6.4 million, respectively. Expenses related to clinical trials pursuant to contracts with research institutions and clinical research organizations represented 46% of Valera s total research and development expense for the year ended December 31, 2005 and 23% of Valera s research and development expense for the year ended December 31, 2005 and 23% of Valera s research and development expense for the year ended December 31, 2005 was attributable to lower stock compensation expense and lower material costs as all costs associated with producing Vantas were carried in inventory and expensed to cost of product sales as Vantas was sold.

*Selling and Marketing Expense*. Valera s selling and marketing expense for the years ended December 31, 2005 and 2004 was \$10.8 million and \$5.0 million, respectively. The increase in the 2005 period over the 2004 period was predominantly the result of an increase in payroll and the related expenses of adding employees to Valera s sales force as well as increased promotional costs resulting from a full year of Vantas promotions. Valera s commercial organization consisted of 41 individuals at December 31, 2005.

*General and Administrative Expense.* Valera's general and administrative expense was \$5.5 million for the year ended December 31, 2005, and \$5.9 million for the year ended December 31, 2004. The decrease from 2004 to 2005 was attributable to a decrease in stock-based compensation. For the years ended December 31, 2005 and 2004, general and administrative expense included a stock-based compensation charge of (\$0.3) million and \$2.3 million, respectively. Without stock-based compensation expense, Valera's general and administrative expenses increased by approximately \$2.2 million from 2004 to 2005 because of hiring of additional personnel, increased regulatory fees, increased legal fees associated with pursuing and maintaining patent protection for Valera's product candidates and other corporate matters, increased accounting fees relative to the increased size of Valera's business and the scope of the audit, bad debt expense and other professional services required to support the hiring of personnel.

*Net Interest Income (Expense).* Valera s net interest income (expense) was \$49,000 for the year ended December 31, 2005 and (\$6,000) for the year ended December 31, 2004. The variance was primarily attributable to slightly greater cash balances, improved cash management and less borrowing under capital leases.

*Income Taxes.* Valera has incurred net operating losses since inception. However, in 2005 Valera generated taxable income as a result of certain temporary and permanent differences between book income and taxable income. As a result Valera recorded an alternative minimum tax provision of \$20,000 for federal purposes and \$55,000 for state taxes.

Valera's deferred tax assets primarily consist of net operating loss carryforwards and research and development tax credits. Valera has recorded a valuation allowance for the full amount of its deferred tax asset, as the realization of the deferred tax asset is uncertain. As of December 31, 2005, Valera had federal net operating loss carryforwards of approximately \$19.4 million. These federal loss carryforwards will begin expiring in 2022 for federal purposes. Annual limitations may result in the expiration of net operating loss and credit carryforwards before they are used. Under the provisions of the Internal Revenue Code, substantial changes in Valera's ownership may limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset taxable income.

### Liquidity and Capital Resources

As of December 31, 2006, Valera s cash and cash equivalents were approximately \$14.1 million, as compared to \$2.3 million at December 31, 2005. The net increases were primarily due to the proceeds Valera received from the initial public offering of its common stock.

Valera s net cash used in operating activities was approximately \$13.7 million for the year ended December 31, 2006. The net cash used in operating activities was attributable to a net loss of approximately \$13.9 million, as adjusted for the effect of non-cash items of \$2.6 million and changes in operating assets and liabilities of approximately \$2.4 million. The changes in operating assets and liabilities consisted of cash inflows from the decrease in accounts receivable and increase in accounts payable, which were more than offset by the building of inventory, increase in prepaid expenses, and decreases in accrued expenses and deferred liabilities.

Valera s net cash used in investing activities was approximately \$4.8 million for the year ended December 31, 2006. The net cash used in investing was attributable to capital expenditures of approximately \$4.2 million related to the construction project to expand Valera s manufacturing capabilities, plus equipment for

the increase in production levels. Valera expects to spend an additional \$0.1 million in the first half of 2007 on the expansion project. In addition, Valera purchased the product rights associated with Valstar for approximately \$0.6 million. Valera purchased and sold approximately \$6.0 million in investments consisting of U.S government and agency securities.

Valera s net cash provided by financing activities was approximately \$30.2 million for the year ended December 31, 2006. As a result of Valera s initial public offering in February 2006, Valera generated approximately \$31.6 million of proceeds net of underwriter fees from the issuance of its common stock and approximately \$100,000 from the issuance of stock as a result of stock option exercises. Valera paid approximately \$1.3 million in offering fees during 2005, resulting in total net proceeds from the initial public offering of \$30.3 million. Subsequent to the initial public offering of its common stock, Valera repaid in full the approximately \$1.5 million outstanding amount under its line of credit with Merrill Lynch.

Valera expects its cash requirements to continue to increase in the foreseeable future as Valera continues to sponsor additional clinical trials, seek regulatory approvals, and develop, manufacture and market Valera s current product candidates. As Valera continues to expand its commercial organization, expand its research and development efforts and pursue additional opportunities, Valera anticipates significant cash requirements for the hiring of personnel, capital expenditures and investment in additional internal systems and infrastructure. The amount and timing of cash requirements will depend on market acceptance of Valera s lead product, Vantas, as well as regulatory approval and market acceptance of Valera s product candidates, if any. The resources Valera devotes to researching, developing, formulating, manufacturing, commercializing and supporting its product candidates, and Valera s ability to enter into third-party collaborations will also affect Valera s cash requirements.

Valera believes that its existing cash, cash generated from future sales of Vantas and Valera's other product candidates, if approved, and Valera's line of credit will be sufficient to fund Valera's operations for at least the next 12 months. Until Valera can generate significant cash from its operations, Valera expects to continue to fund its operations with existing cash resources that were primarily generated from the proceeds of prior offerings of Valera's equity securities. In addition, Valera may receive revenue from its sublicense agreements.

Valera may finance future cash needs through strategic collaboration agreements, the sale of equity securities or additional debt financing. Valera may not be successful in obtaining collaboration agreements, additional debt or equity financing or in receiving milestone or royalty payments under those agreements. In addition, Valera cannot be sure that in the future its existing cash resources will be adequate or that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to Valera or its stockholders. Insufficient funds may require Valera to delay, scale back or eliminate some or all of its research or development programs or delay the launch of its product candidates.

### **Contractual Obligations and Commitments**

The following table summarizes Valera s long-term annual contractual obligations as of December 31, 2006 (in thousands):

	Payments Due in							
Contractual Obligations	Total	2007	2008	2009	2010	2011	Aff	ter 2011
Operating leases	\$11,658	\$ 1,319	\$ 1,319	\$ 1,315	\$ 1,399	\$ 1,484	\$	4,822
Capital lease obligations	23	10	10	3				
Accrued royalties(1)	251	251						
	\$ 11,932	\$ 1,580	\$ 1,329	\$ 1,318	\$ 1,399	\$ 1,484	\$	4,822

(1) Royalty payments have only been determined for 2007 based upon 2006 sales. Future royalties have not been estimated as they are based on future sales levels.

Note: Under the terms of the Plantex agreement, beginning in the calendar year following the year in which Valera receives regulatory approval for Valstar in the United States, Valera will be required to purchase a minimum of \$1,000,000 of Valrubicin each calendar year until the agreement expires. This is not reflected in the above table, since Valera has not received regulatory approval to re-launch Valstar in the United States as of December 31, 2006.

#### **Off-balance Sheet Arrangements**

As of December 31, 2006, Valera did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, Valera does not engage in trading activities involving non-exchange traded contracts. As such, Valera is not materially exposed to any financing, liquidity, market or credit risk that could arise if it had engaged in these relationships.

### **Recent Accounting Pronouncements**

In July 2006, the FASB issued FIN 48 *Accounting for Uncertainty in Income Taxes* which clarifies the accounting for uncertainty in income taxes recognized in an entity s financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. FIN 48 requires an entity to recognize the benefit of tax positions only when it is more likely than not, based on the position s technical merits, that the position would be sustained upon examination by the respective taxing authorities. The tax benefit is measured as the largest benefit that is more than fifty-percent likely of being realized upon final settlement with the respective taxing authorities. FIN 48 is effective for fiscal years beginning after December 15, 2006. FIN 48 is not expected to have a material effect on the results of operations or financial position of Valera.

In September 2006, the FASB issued Statement of Accounting Standards No. 157 (SFAS 157), *Fair Value Measurements*, which defines fair value, establishes guidelines for measurements but eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. Earlier adoption is permitted, provided the company has not yet issued financial statements, including for interim periods, for that fiscal year. Valera is evaluating the impact of SFAS 157, but does not expect the adoption of SFAS 157 to have a material impact on its financial position, results of operations or cash flows.

#### EQUITY COMPENSATION PLAN INFORMATION AS OF DECEMBER 31, 2006

The following table sets forth information as of the end of the Valera s 2006 fiscal year with respect to compensation plans under which Valera is authorized to issue shares.

				Number of Shares	
				Remaining Available for	
				Future Issuance under	
		Weight	ed-Average	Equity Compensation	
	Number of Shares to be Issued Upon	Exer	cise Price	Plans (Excluding	
	Exercise of	of		Securities in 1(st)	
Plan Category	Outstanding Options		standing ions (\$)	Column)	
Equity compensation plan approved by security holders(1)	1,498,163	\$	5.29	283,408	
Equity compensation plans not approved by security holders(2)					
1010015(2)					
Total	1,498,163	\$	5.29	283,408	

<sup>(1) 2003</sup> Equity Incentive Plan.

In September 2002, Valera adopted its Equity Incentive Plan, which was approved by Valera's stockholders in May 2003. Valera's Equity Plan provides for the award of:

restricted shares of Valera common stock;

incentive stock options;

non-qualified stock options; or

any combination of the foregoing.

Grants of restricted shares and non-qualified stock options can be made to Valera's employees, directors, consultants, and other individuals who perform services for Valera. Grants of incentive stock options may only be made to Valera's employees. The principal features of Valera's Equity Incentive Plan are summarized below, but the summary is qualified in its entirety by reference to Valera's Equity Incentive Plan, which was filed as exhibit 10.14 to the Registration Statement in connection with Valera's initial public offering.

### Number of shares of our common stock available under Valera s Equity Plan

Valera has reserved a total of 1,833,333 shares of its common stock for issuance pursuant to its Equity Incentive Plan. Shares subject to forfeited, cancelled, or expired awards and shares received in satisfaction of the exercise price of an option become available for grant again

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<sup>(2)</sup> Valera does not maintain any equity compensation plans that have not been approved by its stockholders.

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under its Equity Incentive Plan. In addition, shares withheld in payment of any exercise price or in satisfaction of any withholding obligation arising in connection with an award granted under Valera's Equity Incentive Plan become available for grant again under its Equity Incentive Plan. In connection with recapitalizations, stock splits, combinations, stock dividends, and other events affecting Valera's common stock, the compensation committee of Valera's board of directors may make adjustments or equitable substitutions it deems appropriate in its sole discretion to the maximum number, type and issuer of the securities reserved for issuance under Valera's Equity Incentive Plan, to the maximum number, type and issuer of shares of Valera's common stock subject to outstanding options, to the exercise price of the options and to the number, type and issuer of restricted shares.

### Administration of Valera s Equity Incentive Plan

Valera s compensation committee administers Valera s Equity Incentive Plan under authority granted to it by Valera s board of directors in accordance with the terms of Valera s Equity Incentive Plan. To administer Valera s Equity Incentive Plan, Valera s compensation committee must consist of at least two members of Valera s board of directors, each of whom is a non-employee director for purposes of Rule 16b-3 under the Exchange Act and, with respect to awards that are intended to constitute performance-based compensation under Section 162(m) of the Internal Revenue Code of 1986, an outside director for the purposes of Section 162(m). Valera s compensation committee, among other things, interprets Valera s Equity Incentive Plan, selects award recipients, determines the type of awards to be granted to such recipients and determines the number of shares subject to each award and the terms and conditions thereof. Valera s compensation committee may also determine if or when the exercise price of an option may be paid in the form of shares of Valera s common stock and the extent to which shares or other amounts payable with respect to an award can be deferred by the participant. Valera s board of directors may amend or modify Valera s Equity Incentive Plan at any time. In addition, Valera s board of directors is also authorized to adopt, alter and repeal any rules relating to the administration of Valera s Equity Incentive Plan and to rescind the authority of Valera s compensation committee and thereafter directly administer Valera s Equity Incentive Plan. However, subject to certain exceptions, no amendment or modification will impair the rights and obligations of a participant with respect to an award unless the participant consents to that amendment or modification.

Valera s Equity Incentive Plan will continue in effect until terminated by Valera in accordance with its terms, although incentive stock options may not be granted more than 10 years after the adoption of Valera s Equity Incentive Plan.

### QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

To date, all of Valera s sales have been denominated in United States dollars, although Valera does conduct some clinical and safety studies with vendors located outside the United States. All of these expenses are paid in U.S. dollars. If the exchange rate undergoes a change of 10%, Valera does not believe that it would have a material impact on its results of operations or cash flows. Accordingly, Valera believes that there is no material exposure to risk from changes in foreign currency exchange rates.

Valera holds no derivative financial instruments and does not currently engage in hedging activities.

Valera s exposure to interest rate risk is related to the investment of Valera s excess cash into highly liquid financial investments with original maturities of three months or less. Valera invests in money market funds in accordance with its investment policy. The primary objectives of Valera s investment policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Valera s investment policy specifies credit quality standards for Valera s investments. Due to the short term nature of Valera s investments, Valera has assessed that there is no material exposure to interest rate risk arising from them.

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### VALERA PHARMACEUTICALS, INC.

### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders

Valera Pharmaceuticals, Inc.

We have audited the accompanying balance sheets of Valera Pharmaceuticals, Inc. as of December 31, 2006 and 2005, and the related statements of operations, shareholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2006. Our audits also included the financial statement schedule listed in the index. These financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Valera Pharmaceuticals, Inc. at December 31, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with United States generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 2 to the financial statements, in 2006 the Company adopted SFAS No. 123(R), Share-Based Payment.

/s/ Ernst & Young LLP

MetroPark, New Jersey

February 16, 2007

### VALERA PHARMACEUTICALS, INC.

### **BALANCE SHEETS**

### (in thousands, except par value)

	Decem 2006	ber 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,069	\$ 2,340
Accounts receivable, net of allowances of \$257 and \$385 at December 31, 2006 and 2005, respectively	2,661	4,488
Inventories, net	5,911	3,191
Prepaid and other current assets	877	726
Total current assets	23,518	10,745
Property, plant and equipment, net	7,849	4,194
Deferred offering costs	.,	1,378
Intangible assets, net of accumulated amortization of \$79 at December 31, 2006	446	,
Other non-current assets	152	215
Total assets	\$ 31,965	\$ 16,532
LIABILITIES AND SHAREHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 2,594	\$ 1,421
Accrued liabilities	3,318	4,607
Note payable		1,525
Deferred revenue current		329
Capital lease obligations current	9	18
Total current liabilities	5,921	7,900
Capital lease obligations long term	13	
Deferred revenue long term	300	300
Commitments and contingent liabilities		
Series A 6% Cumulative Convertible Preferred Stock, \$0.001 par value; 0 and 7,000 shares issued and		
outstanding; liquidation preference \$0 and \$7,598 at December 31, 2006 and 2005, respectively		13,604
Series B 10% Cumulative Convertible Preferred Stock, \$0.001 par value; 0 and 22,069 shares issued and		
outstanding; liquidation preference \$0 and \$20,221 at December 31, 2006 and 2005, respectively		15,082
Series C 6% Cumulative Convertible Preferred Stock, \$0.001 par value; 0 and 11,600 shares issued and		
outstanding; liquidation preference \$0 and \$12,590 at December 31, 2006 and 2005, respectively		11,239
Shareholders equity (deficit):		
Common stock, \$0.001 par value; 30,000 shares authorized, 14,937 and 1,667 shares issued and outstanding at		
December 31, 2006 and 2005, respectively	15	2
Additional paid-in capital	79,316	8,696
Deferred stock-based compensation		(630)
Accumulated deficit	(53,600)	(39,661)
Total shareholders equity (deficit)	25,731	(31,593)
Total liabilities and shareholders equity (deficit)	\$ 31,965	\$ 16,532

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

### VALERA PHARMACEUTICALS, INC.

# STATEMENTS OF OPERATIONS

### (in thousands, except per share amounts)

Net product sales				
Licensing revenue			<sup>3</sup> 3,311 135	
	121	54	155	
Total net revenue	17,966	26,832	5,646	
Operating costs and expenses:				
Cost of product sales	5,107	5,966	608	
Research and development	7,574	5,930	6,376	
Selling and marketing	12,139	10,754	5,025	
General and administrative	8,154	5,500	5,897	
Amortization of intangible assets	79			
Total operating expenses	33,053	28,150	17,906	
Loss from operations	(15,087)	(1,318)	(12,260)	
Interest income	967	70	65	
Interest expense	(26)	(21)	(71)	
Loss before income taxes	(14,146)	(1,269)	(12,266)	
(Benefit from) provision for income taxes	(207)	75	(243)	
Net loss	(13,939)	(1,344)	(12,023)	
Deemed dividend	(15,959)	(1,544)	(5,861)	
			(5,001)	
Net loss attributable to common shareholders	\$ (13,939)	\$ (1,344)	\$ (17,884)	
Basic and diluted net loss per share	\$ (1.03)	\$ (0.81)	\$ (10.73)	
Basic and diluted weighted average number of shares outstanding	13,580	1,667	1,667	

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

### VALERA PHARMACEUTICALS, INC.

### STATEMENTS OF SHAREHOLDERS EQUITY (DEFICIT)

### For the Years Ended December 31, 2004, 2005 and 2006

### (in thousands)

	Comm	on Stoc	k		lditional Paid-in	n	eferred	Ac	cumulated	Sh	Total areholders
	Shares	Par V	alue	-	Capital		pensation		Deficit		ity (Deficit)
Balance at December 31, 2003	1,667	\$	2	\$	5,273		•	\$	(20,433)	\$	(15,158)
Deferred compensation related to stock options, net of											
cancellations					4,637	\$	(4,637)				
Amortization of deferred stock-based compensation							3,104				3,104
Expense related to options granted to non-employees					51						51
Deemed dividend									(5,861)		(5,861)
Net loss									(12,023)		(12,023)
Balance at December 31, 2004	1,667		2		9,961		(1,533)		(38,317)		(29,887)
Exercise of stock options					1						1
Deferred compensation related to stock options, net of											
cancellations					(1,430)		1,430				
Amortization of deferred stock based compensation							(527)				(527)
Expense related to options granted to non-employees					164						164
Net loss									(1,344)		(1,344)
Balance December 31, 2005	1,667		2		8,696		(630)		(39,661)		(31,593)
Issuance of common stock from initial public offering	3,863		4		30,201						30,205
Conversion of preferred stock into common stock	9,356		9		39,916						39,925
Exercise of stock options	51				157						157
Elimination of deferred compensation related to											
adoption of FAS 123(R)					(630)		630				
Expense related to options granted to non-employees					8						8
Compensation expense related to employee stock											
options					968						968
Net loss									(13,939)		(13,939)
Balance at December 31, 2006	14,937	\$	15	\$	79,316	\$		\$	(53,600)	\$	25,731

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

### VALERA PHARMACEUTICALS, INC.

### STATEMENTS OF CASH FLOWS

### (in thousands)

	Year 1 2006	Ended Decemb 2005	oer 31, 2004
Operating activities			
Net loss	\$ (13,939)	\$ (1,344)	\$ (12,023)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization	673	502	257
Amortization of deferred financing costs	68	11	
Allowances for accounts receivable	840	294	91
Expense related to options granted to non-employees	8	164	51
Stock-based compensation	968	(527)	3,104
Change in assets and liabilities:			
Accounts receivable	987	476	(5,006)
Other accounts receivable			574
Inventories	(2,720)	(1,826)	(1,365)
Restricted cash		100	(100)
Prepaid and other current assets	(151)	(584)	(50)
Security deposits		(46)	362
Accounts payable	1,173	(621)	856
Accrued liabilities	(1,289)	3,055	1,107
Deferred revenue	(329)	629	
Net cash (used in) provided by operating activities	(13,711)	283	(12,142)
Investing activities	(13,711)	205	(12,142)
Capital expenditures	(4,221)	(2,992)	(1,610)
Purchase of product rights	(4,221)	(2,992)	(1,010)
Purchase of investment in Spepharm	(525)		
Purchase of investments held-to-maturity	(6,000)		
Proceeds from the sale of investments held-to-maturity	6,000		
Troceeds from the safe of investments neu-to-maturity	0,000		
Net cash used in investing activities	(4,751)	(2,992)	(1,610)
Financing activities			
Net proceeds from issuance of common stock	31,740	1	
Payment of capital lease obligations	(24)	(17)	(31)
Proceeds from note payable		1,525	
Payment of notes payable	(1,525)		
Deferred offering costs		(1,378)	
Deferred financing costs		(135)	
Proceeds from officer loan			200
Repayment of officer loan			(200)
Net proceeds from issuance of convertible preferred stock			13,595
Net cash provided by (used in) financing activities	30,191	(4)	13,564
Net increase (decrease) in cash and cash equivalents	11,729	(2,713)	(188)
Cash and cash equivalents at beginning of period	2,340	5,053	5,241
Cash and cash equivalents at end of period	\$ 14,069	\$ 2,340	\$ 5,053

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Supplemental Disclosure of Cash Flow Information and Non-Cash Investing and Financing Activities				
Cash paid for interest	\$	26	\$ 20	\$ 65
Cash paid for income taxes	\$	95	\$ 11	
Deemed dividends on preferred stock				\$ 5,861
Conversion of preferred stock into common stock	\$ 3	9,925		
Acquisition of an asset through a capital lease	\$	28		

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

### VALERA PHARMACEUTICALS, INC.

#### NOTES TO FINANCIAL STATEMENTS

#### Note 1. Organization and Description of Business

#### Nature of Operations

Valera Pharmaceuticals, Inc. (Valera or the Company), is a specialty pharmaceutical company focused on the development, acquisition and commercialization of products for the treatment of urological and endocrine conditions, diseases and disorders, including products that utilize its Hydron implant proprietary technology. The Company s headquarters and manufacturing operations are located in Cranbury, New Jersey. Valera was incorporated in the state of Delaware on May 30, 2000.

On February 7, 2006, the Company closed its initial public offering. The Company issued 3,862,500 shares at \$9.00 per share resulting in net proceeds of \$30.3 million after underwriter s discounts and offering expenses. As a result of the initial public offering, all shares of the Company s preferred stock converted into 9,355,714 shares of common stock. Thus, immediately following the offering the Company had 14,885,296 common shares outstanding. In February 2006, the Company paid in full its note payable to Merrill Lynch in the amount of \$1.5 million.

In December 2006, we entered into a merger agreement with Indevus Pharmaceuticals pursuant to which Indevus will acquire us in a tax-free stock-for-stock merger transaction. Pursuant to the Merger Agreement, upon the closing of the merger, each outstanding share of our common stock (other than shares held by us or Indevus or any stockholders who properly exercise dissenters rights under Delaware law), will automatically be converted into the right to receive a number of shares of Indevus common stock equal to \$7.75 divided by the volume weighted average of the closing prices of Indevus common stock during the 25 trading days ending on the fifth trading day prior to the date of our stockholders meeting to consider the merger, or the Indevus Common Stock Value. The exchange ratio is subject to a collar such that if the Indevus Common Stock Value falls outside of the collar the exchange ratio will become fixed. If the Indevus Common Stock Value is greater than \$8.05, then the exchange ratio will be 0.9626, and if it is less than \$6.59, then the exchange ratio will be 1.1766. Cash will be paid in lieu of fractional shares.

In addition, each share of the Company s common stock will be converted into three contingent stock rights, or CSRs, relating to three of the Company s product candidates. One CSR will be convertible into \$1.00 of Indevus common stock upon FDA approval of Supprelin-LA, provided sufficient quantities of Supprelin-LA are then available, one CSR will be convertible into \$1.00 of Indevus common stock upon FDA approval of the Company s biodegradable ureteral stent and one CSR will be convertible into \$1.50 of Indevus common stock upon FDA approval of the Company s octreotide implant. The amount of Indevus common stock into which the CSRs will convert will be determined by a formula based on the average stock price of Indevus prior to achievement of the applicable milestones. The CSRs will convert into Indevus common stock only if the applicable milestones are achieved within three years of the closing of the merger in the case of Supprelin-LA and within five years of the closing of the merger in the case of the Company s biodegradable ureteral stent and one the company s biodegradable ureteral stent and octreotide implant. If the merger is not completed for any reason, the Company might have to pay Indevus a termination fee of \$5.0 million, or the Company might be required to reimburse Indevus for up to \$3.0 million of expenses related to the merger, such as legal, accounting, financial advisory and printing fees.

Separately, the Company entered into a co-promotion agreement with Indevus pursuant to which Indevus sales force will co-promote Vantas in the United States. Under the terms of the agreement, the Company will be required to make royalty payments to Indevus of 13.5% on sales of Vantas up to a specified unit level, which will increase to 30% for sales above the specified level. Indevus will also receive royalties of 35% for sales of Vantas to specified specialty pharmacy accounts. The co-promotion began in January 2007.

#### VALERA PHARMACEUTICALS, INC.

#### NOTES TO FINANCIAL STATEMENTS (Continued)

#### **Reverse Stock Split**

On January 27, 2006, the Company effected a one-for-six reverse stock split. In connection with the reverse stock split, every outstanding six shares of the Company s common stock were replaced with one share of the Company s common stock. All references to common stock, common shares outstanding, average number of common shares outstanding and per share amounts in these consolidated financial statements and notes to consolidated financial statements prior to the effective date of the reverse stock split have been restated to reflect the one-for-six reverse stock split on a retroactive basis. Effective upon consummation of the initial public offering, the Company reduced the number of common shares authorized for issuance to 30,000,000 and the number of preferred shares authorized for issuance to 5,000,000.

#### Note 2. Basis of Presentation and Significant Accounting Policies

#### Use of estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

#### Reclassifications

Certain reclassifications have been made to the prior period s financial information to conform to the December 31, 2006 presentation. Deferred financing costs and security deposits in the prior year presentation have been combined into the other non current assets category in the current presentation.

#### Cash and Cash Equivalents

The Company considers all highly liquid instruments purchased with a maturity of three months or less to be cash and cash equivalents. At December 31, 2006 and 2005, the Company had substantially all of its cash and cash equivalents deposited with two financial institutions.

#### Investments Held-to-Maturity

During fiscal 2006, the Company purchased investments in certain debt securities that were classified as investments held-to-maturity in accordance with SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. Investments held-to-maturity are recorded on the balance sheet at cost. Realized gains and losses on sales of investments are determined using the specific identification method. As of December 31, 2006, all investments in certain debt securities that were purchased during the year, matured and were sold. The total amount of investments purchased and sold during fiscal year 2006 was \$6,000,000. No realized gains or loss were recognized on the transactions.

#### Allowances for Accounts Receivable

The Company maintains allowances for accounts receivable, which include an allowance for doubtful accounts related to the estimated losses that may result from the inability of its customers to make required payments. This allowance is determined based upon historical experience and any specific customer collection issues that have been identified. The Company began selling its first product on November 8, 2004 and has not experienced significant credit losses related to an individual customer or groups of customers in any particular industry or geographic area. Also included in the allowances for accounts receivable is an allowance for early payment discounts.

#### VALERA PHARMACEUTICALS, INC.

#### NOTES TO FINANCIAL STATEMENTS (Continued)

#### Inventory

The Company values its inventory at the lower of cost (determined by the first-in, first-out method) or market. The Company regularly reviews inventory quantities on hand and records a provision for excess and obsolete inventory based primarily on estimated forecasts of product demand and production requirements. The Company s estimate of future product demand may prove to be inaccurate, in which case it may have understated or overstated the provision required for excess and obsolete inventory. In the future, if the Company s inventory is determined to be overvalued, the Company would be required to recognize such costs in costs of product sales at the time of such determination. Likewise, if the inventory is determined to be undervalued, the Company may have recognized excess cost of product sales in previous periods and would be required to recognize such additional operating income at the time of sale.

#### Property, Plant and Equipment

Property, plant and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, generally three to seven years. Leasehold improvements and capitalized leases are recorded at the fair market value at the inception of the leases and are amortized over the shorter period of their estimated useful life or the lease ranging from five to ten years. Amortization of assets recorded under capital leases is included in depreciation and amortization expense.

#### **Deferred Offering and Financing Costs**

Costs incurred in relation to the Company s initial public offering were deferred as of December 31, 2005 and were recognized and netted against gross proceeds raised in the offering that was completed in February 2006. Costs incurred in relation to the Company s line of credit were deferred and are being amortized over the two-year term of the loan and are included in other non current assets.

#### Investment Spepharm

On July 17, 2006, the Company entered into an Investment and Shareholders Agreement in which the Company received a 19.9% ownership interest in a newly created Dutch company called Spepharm Holding B.V. (Spepharm) for a nominal amount of approximately \$5,000. Spepharm and its European specialty pharmaceutical group of companies are focusing on becoming one of the leading suppliers of specialty urology and endocrinology products to the European market place. In accordance with APB 18 The Equity Method of Accounting for Investment in Common Stock and FIN 35 Criteria for Applying the Equity Method of Accounting for Investment in Common Stock the Company has recorded the investment as a long term investment and is applying the cost method for the accounting of the investment. Under the cost method, the investment is recorded at its original cost. It continues to be carried and reported at cost until it is either partially or entirely disposed, or until some fundamental change in conditions makes it clear that the value originally assigned can no longer be justified. The investment is included in other non current assets.

#### Net Product Sales

Net product sales are presented net of estimated returns and price adjustments, prompt pay discounts, group purchasing fees and credit card fees.

#### **Revenue Recognition**

The Company s revenue recognition policies are in accordance with Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition in Financial Statements (SAB 104), and

### VALERA PHARMACEUTICALS, INC.

#### NOTES TO FINANCIAL STATEMENTS (Continued)

SFAS No. 48, Revenue Recognition When Right of Return Exists (SFAS 48), which provides guidance on revenue recognition in financial statements, and is based on the interpretations and practices developed by the Securities and Exchange Commission. SFAS 48 and SAB 104 require that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the seller s price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured. Determination of criteria (3) and (4) are based on management s judgments regarding the fixed nature of the fee charged for services rendered and products delivered and the collectibility of those fees. Should changes in conditions cause management to determine that these criteria are not met for certain future transactions, revenue recognition for those transactions will be delayed and the Company s revenue could be adversely affected.

Allowances have been recorded for any potential returns or adjustments in accordance with the Company s policy. Returns are allowed for damaged or outdated goods. As of December 31, 2006, we had a reserve of approximately \$143,000 for returns and adjustments, of which \$143,000 related to sales made in 2006. As of December 31, 2006 and 2005, there was approximately \$40,000 and \$300,000 of retail value of Vantas, respectively, at distributors.

	Distributors	Physicians (In thousands)	Total
Balance at 12/31/2004	\$ 28	\$ 316	\$ 344
Provision related to sales made in current period	20	2,175	2,195
Provision related to sales made in prior periods			
Returns and adjustments	(29)	(2,171)	(2,200)
Balance at 12/31/2005	19	320	339
Provision related to sales made in current period	19	1,006	1,025
Provision related to sales made in prior periods		58	58
Returns and adjustments	(34)	(1,245)	(1,279)
Balance at 12/31/2006	\$ 4	\$ 139	\$ 143

#### Customer Sales Urologists

The Company s revenue from product sales is recognized when there is persuasive evidence an arrangement exists, the price is fixed in accordance with the Company s Customer Price List and/or approved exception pricing, or determinable from executed contracts, delivery to the customer has occurred and collectibility is reasonably assured. The Company uses contracts, purchase orders, sales orders directly taken by product specialists and sales order confirmations to determine the existence of an arrangement. Title to the product is taken upon delivery of the product, at which time risk of loss shifts to the customer. Billing does not take place until the day after shipment has occurred. The Company uses shipping documents and, the Company is provided with third party proof of delivery to verify delivery to its customers.

#### **Customer Sales Distributor Sales**

With respect to sales to distributors, revenue is recognized upon shipment, as the title, risks and rewards of ownership of the products pass to the distributors and the selling price of the Company s product is fixed and determinable at that point, as long as the Company believes the product will be sold by the distributor within one to three months from the shipment of the product by the Company to the distributor. If the Company believes the product will be deferred until the product is sold and the product held by the distributor will be classified as an asset on the Company s financial statements until it is sold by the

#### VALERA PHARMACEUTICALS, INC.

#### NOTES TO FINANCIAL STATEMENTS (Continued)

distributor. As of December 31, 2006 and 2005, the Company deferred approximately \$0 and \$329,000 of revenue, respectively, and recorded \$0 and \$44,000 of inventory on consignment, respectively. The 2005 amounts related to product sold to distributors in the fourth quarter of 2005 that were not resold by distributors in accordance with the Company s policy. Payment is due based upon the agreed terms of the contract. The distributor is responsible for selling and distributing the product to its customer base and the rights for return are restricted to the Company s published return policy in effect for all customers.

#### Royalties

Licensing revenue from royalty arrangements are recorded on a cash basis due to the uncertainties regarding calculations, timing and collections. Royalty expense is recorded as the corresponding revenue is recognized. Royalty expense is included in cost of product sales in the statement of operations.

#### Shipping and Handling Costs

Shipping and handling costs incurred for inventory purchases and product shipments are included within cost of product sales in the statements of operations.

#### **Research and Development**

Costs incurred in connection with research and development activities are expensed as incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform research for the Company. Research and development expenditures are charged to operations as incurred. Our expenses related to clinical trials are based on actual and estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses related to clinical trials generally are accrued based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates accordingly on a prospective basis.

#### Advertising Costs

The Company charges advertising costs to selling and marketing expense as incurred. Advertising expense was approximately \$1.2 million, \$1.0 million and \$1.3 million for the years ended December 31, 2006, 2005 and 2004, respectively

#### Intangible Assets

On March 31, 2006, the Company completed its acquisition of the product rights associated with the product known as Valstar (valrubicin) in the United States and Valtaxin in Canada. As of December 31, 2006, the Company has an intangible asset of approximately \$446,000 associated with such product rights. The intangible asset was recorded at its original cost of \$525,000, less accumulated amortization of approximately \$79,000 as of December 31, 2006. Intangible assets are stated at cost, less accumulated amortization, and are amortized over their estimated useful lives using the straight-line method. The Company estimates that the useful life of the Valstar product rights is 5 years. The Company periodically reviews the original estimated useful lives of long-lived assets and their carrying amounts and makes adjustments when appropriate if there are any indications of impairment.

#### VALERA PHARMACEUTICALS, INC.

#### NOTES TO FINANCIAL STATEMENTS (Continued)

#### **Stock-Based Compensation**

The Company adopted SFAS No. 123(R), *Shared-Based Payment* on January 1, 2006. SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. Under SFAS 123(R), the options the Company granted in prior years as a non-public company (prior to the initial filing of its Registration Statement in March 2005) that were valued using the minimum value method, were not expensed in 2006 and will not be expensed in future periods. Options granted as a non-public company and accounted for using the intrinsic value method (cheap stock), will continue to be expensed over the vesting period. The Company adopted the prospective transition method for these options. Options granted as a public company are expensed under the modified prospective method.

SFAS No. 123(R) does not change the accounting guidance for how the Company accounts for options issued to non-employees. The Company accounts for options issued to non-employees under SFAS No. 123 and EITF Issue No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. As such, the value of such options is periodically re-measured and income or expense is recognized during their vesting terms.

#### **Deferred Stock Compensation**

At December 31, 2005, the Company had deferred stock compensation of approximately \$630,000. In accordance with the adoption of FAS 123(R), all deferred compensation related to employee stock options has been eliminated. As of December 31, 2006, the deferred compensation balance was \$0.

#### Income Taxes

The Company utilizes the asset and liability method specified by Statement of Financial Accounting Standards No. 109 (SFAS 109), *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

#### Long-lived Assets

The Company assesses the recoverability of long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the fair value to the carrying value. There have been no indicators of impairment through December 31, 2006.

#### **Concentration Risks**

The financial instrument that potentially subjects the Company to concentration of credit risk is cash. The Company places its cash with high-credit quality financial institutions. Concentrations of credit risk, with respect to this financial instrument, exist to the extent of amounts presented in the financial statements.

In 2006, 2005 and 2004, the Company generated all of its product sales from Vantas. In addition, for the years ended December 31, 2006 2005 and 2004, one customer accounted for 6%, 6% and 9%, respectively, of the Company s net unit sales and 5%, 0% and 11.6% of its outstanding receivables at December 31, 2006, 2005 and 2004, respectively.

#### VALERA PHARMACEUTICALS, INC.

#### NOTES TO FINANCIAL STATEMENTS (Continued)

The Company is dependent on single suppliers for certain raw materials, including histrelin, the active pharmaceutical ingredient in Vantas and Supprelin-LA, and valuability, the active pharmaceutical ingredient in Valstar. The Company does not have an agreement with the supplier of histrelin.

#### Fair Value of Financial Instruments

The carrying amounts of the Company s financial instruments, which include cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate their fair values.

#### **Preferred Stock Dividends**

The Company records deemed dividends when modifications to its preferred stock are required in accordance with EITF 98-5 and EITF 00-27. Such modifications occurred in 2004 resulting in deemed dividends of approximately \$5.9 million. There were no modifications for the years ended December 31, 2006 and 2005, respectively.

#### **Recent Accounting Pronouncements**

In July 2006, the FASB issued FIN 48 *Accounting for Uncertainty in Income Taxes* which clarifies the accounting for uncertainty in income taxes recognized in an entity s financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. FIN 48 requires an entity to recognize the benefit of tax positions only when it is more likely than not, based on the position s technical merits, that the position would be sustained upon examination by the respective taxing authorities. The tax benefit is measured as the largest benefit that is more than fifty-percent likely of being realized upon final settlement with the respective taxing authorities. FIN 48 is effective for fiscal years beginning after December 15, 2006. FIN 48 is not expected to have a material effect on the results of operations or financial position of the Company.

In September 2006, the FASB issued Statement of Accounting Standards No. 157 (SFAS 157), *Fair Value Measurements*, which defines fair value, establishes guidelines for measurements but eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. Earlier adoption is permitted, provided the company has not yet issued financial statements, including for interim periods, for that fiscal year. The Company is evaluating the impact of SFAS 157, but does not expect the adoption of SFAS 157 to have a material impact on the Company s financial position, results of operations or cash flows.

#### Note 3. Inventory

Inventories consist of the following:

	Decem	ber 31,
	2006	2005
	(In tho	usands)
Raw Materials	\$ 583	\$ 463
Work in process	4,411	2,426
Finished goods	917	302
	\$ 5,911	\$ 3,191

The preceding amounts are net of inventory reserves of approximately \$1.2 million at December 31, 2006 and 2005, respectively, for certain products that failed to meet the Company s quality control specifications.

### VALERA PHARMACEUTICALS, INC.

### NOTES TO FINANCIAL STATEMENTS (Continued)

#### Note 4. Property, Plant and Equipment

Property, plant and equipment consists of the following:

	Useful Lives	Decemb 2006 In thousands)	oer 31, 2005
Laboratory equipment	5 years	\$ 1,942	\$ 1,531
Furniture and fixtures	7 years	437	161
Office equipment	5 years	145	108
Computer equipment	3 years	483	417
Computer software	3 years	301	200
Construction in process		3,536	2,526
Leasehold improvements	1-10 years	2,973	625
		9,817	5,568
Less accumulated depreciation and amortization		(1,968)	(1,374)
Property, plant and equipment, net		\$ 7,849	\$ 4,194

Depreciation and amortization expense for property, plant and equipment was approximately \$594,000, \$502,000, and \$257,000, for the years ended December 31, 2006, 2005 and 2004, respectively. There were fixed assets totaling approximately \$95,000 and \$68,000 at December 31, 2006 and 2005, respectively, subject to capital lease obligations with accumulated amortization of approximately \$71,000 and \$54,000 as of December 31, 2006 and 2005, respectively.

### Note 5. Accrued Liabilities

Accrued liabilities consist of the following:

	20	Deceml 2006 (In thou		005
Accrued compensation, bonus and benefits	\$	587	\$	587
Accrued clinical fees		532		312
Accrued financial advisory fees		500		
Accrued other		435		236
Accrued legal fees		358		769
Accrued royalties		238		396
Accrued commissions		231		451
Accrued auditing fees		182		251
Accrual for sales returns and adjustments		143		339
Accrued marketing expenses		108		316
Accrued income taxes		4		75
Accrued distributor chargebacks				621
Accrued printing fees				254

\$ 3,318 \$ 4,607

### VALERA PHARMACEUTICALS, INC.

### NOTES TO FINANCIAL STATEMENTS (Continued)

#### Note 6. Capital Lease Obligations

The minimum future lease payments related to capital leases at December 31, 2006 are as follows (in thousands):

2007	\$ 10
2008	10
2009	3
Total minimum lease payments	23
Less amount representing interest payments	1
Less amount representing interest payments	1
Less amount representing interest payments	1

#### Note 7. Credit Line Agreement

In October 2005, the Company entered into a two-year, \$7,500,000 line of credit with Merrill Lynch Capital. Under the line of credit, the amount the Company may borrow at any given time is dependent upon its accounts receivable balance and related aging of such accounts. In June 2006, the line of credit was amended for interest, covenant and operational terms. Borrowings under the amended line of credit bear an initial interest rate at the sum of the one-month LIBOR rate plus 3.25% (8.58% at December 31, 2006). The Company is subject to certain covenants under the credit agreement. In connection with the credit agreement, the Company pledged all of its assets, with the exception of intellectual property, to Merrill Lynch. As of December 31, 2006 and 2005, the Company had \$0 and approximately \$1.5 million outstanding under the line of credit. The interest rate on the outstanding balance was 8.14% at December 31, 2005. In February 2006, the Company used a portion of the net proceeds from its initial public offering to repay amounts outstanding under the line of credit.

### Note 8. Commitments

The Company leases its facilities and certain equipment under non-cancellable operating lease agreements. The minimum future lease payments under these leases are as follows (in thousands):

Year ending December 31:	
2007	\$ 1,319
2008	1,319
2009	1,315
2010	1,399
2011	1,484
Thereafter	4,822

\$11,658

Total rent expense was approximately \$1.6 million, \$1.4 million, and \$0.7 million, for the years ended December 31, 2006, 2005 and 2004, respectively. The Company s building lease expires March 31, 2015, and the equipment lease expires February 2009. The Company s building lease includes escalation clauses that go into effect in 2009 and 2010, which will result in greater rent payments from 2009 to 2015. The Company records rent expense on a straight-line basis over the term of the lease. The Company has two 5-year renewal options under its building lease.

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The Company is a party to certain agreements that require the Company to pay royalties to third parties based on certain net product sales. For the years ended December 31, 2006, 2005 and 2004, the Company incurred royalty expense of approximately \$0.9 million, \$1.3 million and \$0.3 million, respectively. Future royalties are dependent on future sales levels.

#### VALERA PHARMACEUTICALS, INC.

#### NOTES TO FINANCIAL STATEMENTS (Continued)

#### **Purchase Commitments**

On May 17, 2006, the Company entered into a supply agreement with Plantex USA Inc. whereby Plantex would supply the Company with the active pharmaceutical ingredient ( API ) N-Trifluroacetyl-adriamycin-14 valerate, otherwise known as Valrubicin, in connection with the Company s anticipated launch of the product Valstar for the treatment of bladder cancer. Under the agreement, the Company will only source API from Plantex in connection with the development, manufacture or sale of, and securing regulatory approval for, Valstar in the United States, its territories and possessions, and Canada (the Territory ). Plantex will manufacture and supply all of the Company s requirements for API for commercial sale of Valstar in the Territory. Under the terms of the agreement, beginning in the calendar year following the year in which the Company receives regulatory approval to re-launch Valstar in the United States, the Company will be required to purchase a minimum of \$1.0 million of Valrubicin each calendar year until the agreement expires. The agreement will expire ten years after the date of the first commercial sale of Valstar.

#### Note 9. Capitalization

#### **Reverse Stock Split**

On January 27, 2006, the Company effected a one-for-six reverse stock split. In connection with the reverse stock split, every outstanding six shares of the Company s common stock were replaced with one share of the Company s common stock. All references to common stock, common shares outstanding, average number of common shares outstanding and per share amounts in these financial statements and notes to financial statements prior to the effective date of the reverse stock split have been restated to reflect the one-for-six reverse stock split on a retroactive basis. Effective upon consummation of the initial public offering, the Company reduced the number of common shares authorized for issuance to 30,000,000.

#### **Common Stock**

The Company had 14,936,641 and 1,667,082 shares of common stock outstanding at December 31, 2006 and 2005, respectively. The Company is authorized to issue 30,000,000 shares of common stock with a par value of \$0.001 per share. Each holder of common stock is entitled to one vote of each share of common stock held of record on all matters on which stockholders generally are entitled to vote.

In February 2006, the Company closed its initial public offering in which it issued 3,862,500 shares of its common stock at \$9.00 per share. In conjunction with this offering all of the Company s preferred stock converted into 9,355,714 shares of common stock. As a result, the Company had 14,885,296 shares of common stock outstanding after the closing its initial public offering. During the twelve months ended December 31, 2006, 51,345 shares of common stock were issued as a result of stock option exercises.

Holders of shares of the Company s common stock are entitled to one vote for each share held of record on all matters to be voted on by stockholders. There is no cumulative voting with respect to the election of directors. The holders of the Company s common stock are entitled to receive dividends when, as and if declared by the board of directors out of funds legally available therefore subject to the rights of any class of stock having a preference as to dividends. Under the Company s credit agreement with Merrill Lynch Capital, the Company agreed to not declare or pay any cash dividends.

In the event of a liquidation, dissolution or winding up of us, the holders of the Company s common stock are entitled to share ratably in all assets remaining available for distribution to them after payment of liabilities and after provision has been made for each class of stock, if any, having preference over the common stock. Holders of common stock have no conversion, preemptive or other subscription rights, and there are no

#### VALERA PHARMACEUTICALS, INC.

#### NOTES TO FINANCIAL STATEMENTS (Continued)

redemption provisions applicable to the common stock. The rights, preferences and privileges of holders of common stock are subject to and may be affected by, the rights of the holders of any shares of preferred stock that we may designate and issue in the future.

#### **Convertible Preferred Stock**

All of the Company s outstanding preferred stock was converted into common stock in conjunction with the initial public offering. In February 2006, the Company filed an amended and restated Certificate of Incorporation that removed the designations, rights and preferences of the convertible preferred stock. Effective upon consummation of the initial public offering, the Company reduced the number of the number of preferred shares authorized for issuance to 5,000,000.

#### Note 10. Stock-Based Compensation

In September 2002, the Company adopted the Valera Pharmaceuticals Equity Incentive Plan, which provides for the granting of nonqualified and incentive stock options, as defined by the Internal Revenue Code, to key employees of the Company at prices not less than the fair market value at the date of grant for incentive stock options granted. The option price for each share of common stock for non-qualified options is determined by the board of directors and may be more or less than the fair market value of a share of common stock. The options granted by the Company generally have a life of ten years and vest over a period as determined by the board of directors, which is typically four years.

The Company adopted SFAS No. 123(R), *Shared-Based Payment* on January 1, 2006. SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. Under SFAS 123(R), the options the Company granted in prior years as a non-public company (prior to the initial filing of its Registration Statement in March 2005) that were valued using the minimum value method, were not expensed in 2006 or will not be expensed in future periods. Options granted as a non-public company and accounted for using the intrinsic value method (cheap stock), will continue to be expensed over the vesting period. The Company adopted the prospective transition method for these options. Options granted as a public company are expensed under the modified prospective method.

SFAS No. 123(R) does not change the accounting guidance for how the Company accounts for options issued to non employees. The Company accounts for options issued to non-employees under SFAS No. 123 and EITF Issue No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. As such, the value of such options is periodically re-measured and income or expense is recognized during their vesting terms.

Under the modified-prospective-transition method, under SFAS No. 123(R), the Company is required to record compensation expense for all awards granted after the date of adoption and for the unvested portion of previously granted awards that remain outstanding as of the beginning of the period of adoption. The Company measured stock-based compensation using the Black Scholes option pricing model.

The following ranges of assumptions were used to compute employee stock-based compensation:

Risk- free interest rate	3.90% - 5.01%
Expected volatility	61.1% - 66.15%
Expected dividend yield	0.0%
Expected life (in years)	6.25
Forfeiture rate	0% - 13%
Weighted average fair value at date of grant	\$6.10

#### VALERA PHARMACEUTICALS, INC.

#### NOTES TO FINANCIAL STATEMENTS (Continued)

Expected volatility is based upon an appropriate peer group within the Company s industry sector. The expected life of the awards represents the period of time that options granted are expected to be outstanding.

At December 31, 2006, the Company changed its estimated employee forfeiture rate from 4% to 13% as a result of greater than expected actual stock option forfeitures during 2006. The Company used the most up-to-date historical information to estimate forfeitures in the valuation model. As a result of the change in the forfeiture rate, the Company recorded approximately \$72,000 of income and decreased the loss per share, basic and diluted by \$0.01 as a result of the revised cumulative stock based compensation adjustment.

The risk-free rate for periods within the expected life of the option is based on implied yields on U.S. Government Issues in effect at the time of grant. Compensation cost is recognized using a straight-line method over the vesting or service period and net of estimated forfeitures.

The following table presents all employee stock based compensation costs recognized in the Company s statements of operations:

	Yea	Year Ended December 31,		
	2006	2006 2005		
		(in thousands	5)	
Employee Stock-Based Compensation under Intrinsic Value Method	\$ 192	\$ (527)	\$ 3,104	
Employee Stock-Based Compensation under Fair Value Method	776			
Total Employee Stock-Based Compensation	\$ 968	\$ (527)	\$ 3.104	

In 2005, as a result of the Company s marked to market of previous re-priced options, the Company had to reverse previous recorded stock-based compensation.

The incremental employee stock-based compensation recognized in connection with the adoption of SFAS 123(R) increased the pre-tax and after-tax loss for the year ended December 31, 2006, by approximately \$776,000, and increased the loss per share, basic and diluted by \$(0.06).

The following table illustrates the pro-forma effect on net income per share if the Company recorded compensation expense based on the fair value method for all employee stock-based compensation awards:

	Year Ended	December 31,
	2005	2004
	(in tho	usands)
Net loss attributable to common stock holders as reported	\$ (1,344)	\$ (17,884)
Add: non-cash employee compensation as reported	(527)	3,104
Deduct: total employee stock-based compensation expense determined under fair value based		
method for all awards	(750)	(302)
Net income to common stockholders pro-forma	\$ (2,621)	\$ (15,082)
Basic and diluted net loss per share as reported	\$ (0.81)	\$ (10.73)
Basic and diluted net loss per share pro-forma	\$ (1.57)	\$ (9.05)

### VALERA PHARMACEUTICALS, INC.

### NOTES TO FINANCIAL STATEMENTS (Continued)

The fair value of the options was estimated at the date of grant using the minimum value pricing model with the following assumptions:

		Year Ended December 31, 2005		
	Public	Non-Public		
Risk-free interest rate	4.27%	3.90%	4.24%	
Dividend yield	0%	0%	0%	
Volatility	61%	0%	0%	
Expected lives (in years)	6.3	4.0	4.0	
		1 21 2004 2005	1 200	

The following table summarizes option activity for the Company s common stock for the years ended December 31, 2004, 2005, and 2006.

	Common	We	eighted-			
	Stock	Α	verage	Δσσ	regate	Weighted Average
	Options		xercise Price	Inti Va	rinsic alue ousands)	Contractual Life
Outstanding at December 31, 2003	772,193	\$	3.00			
Granted	353,832	\$	3.00			
Exercised						
Forfeited	(6,600)	\$	3.00			
Outstanding at December 31, 2004	1,119,425	\$	3.00			
Granted	193,594	\$	11.55			
Exercised	(417)	\$	3.00			
Forfeited	(46,753)	\$	4.45			
Outstanding at December 31, 2005	1,265,849	\$	4.25			
Granted	390,200	\$	8.74			
Exercised	(51,345)	\$	3.05			
Forfeited	(106,541)	\$	6.73			
Outstanding at December 31, 2006	1,498,163	\$	5.29	\$	607	7.6
Exercisable at December 31, 2006	791,730	\$	3.51	\$	279	6.9

The total intrinsic value of the options exercised during the year ended December 31, 2006 was \$125,131. The Company received approximately \$157,000 of cash from stock option exercises during the year ended December 31, 2006. As of December 31, 2006, there was approximately \$2.4 million of total employee unrecognized compensation cost related to non-vested stock-based compensation awards granted under the Plan. That cost is expected to be recognized over a weighted average period of three years.

For the years ended December 31, 2004, 2005 and 2006 the Company granted a total of 5,000, 10,833 and 0 options, respectively, to certain consultants. The Company has accounted for non-employee options in accordance with EITF 96-18 and, accordingly, recorded non-cash expense of approximately \$51,000, 164,000 and \$8,000 for the years ended December 31, 2004, 2005 and 2006 respectively.

### VALERA PHARMACEUTICALS, INC.

### NOTES TO FINANCIAL STATEMENTS (Continued)

During the twelve month period ended December 31, 2006, the Company granted stock options with exercise prices as follows:

Number of Options Granted	Weighted Average Exercise Price		Fair V	alue per	Weighted Average Intrinsic Value per Share
220,600	\$	9.08	\$	5.57	
122,100	\$	8.96	\$	5.87	
7,500	\$	7.36	\$	4.79	
40,000	\$	6.45	\$	4.71	
390,200	\$	8.74	\$	5.56	
	Options           Granted           220,600           122,100           7,500           40,000	Options         Ave           Granted         Exerci           220,600         \$           122,100         \$           7,500         \$           40,000         \$	Options         Average           Granted         Exercise Price           220,600         \$ 9.08           122,100         \$ 8.96           7,500         \$ 7.36           40,000         \$ 6.45	Options         Average         Fair V           Granted         Exercise Price         SI           220,600         \$ 9.08         \$           122,100         \$ 8.96         \$           7,500         \$ 7.36         \$           40,000         \$ 6.45         \$	Options         Average         Fair Value per           Granted         Exercise Price         Share           220,600         \$ 9.08         \$ 5.57           122,100         \$ 8.96         \$ 5.87           7,500         \$ 7.36         \$ 4.79           40,000         \$ 6.45         \$ 4.71

During the twelve month period ended December 31, 2005, the Company granted stock options with exercise prices as follows:

Grants Made During Quarter Ended	Number of Options Granted		Weighted Weighted Aver Average Fair Value po xercise Price Share		Value per	Av Intrin	eighted verage sic Value • Share
March 31, 2005	14,499	\$	6.00	\$	16.20	\$	10.20
June 30, 2005	143,594	\$	12.00	\$	12.00		
September 30, 2005	4,334	\$	12.00	\$	12.00		
December 31, 2005	31,167	\$	12.00	\$	12.00		
Total	193,594	\$	11.55	\$	12.31		

During the twelve month period ended December 31, 2004, the Company granted stock options with exercise prices as follows:

Grants Made During Quarter Ended March 31, 2004	Number of Options Granted	Av	ighted erage ise Price	Fair	ted Average Value per Share	A <sup>.</sup> Intrii	eighted verage 1sic Value r Share
June 30, 2004	833	\$	3.00	\$	4.80	\$	1.80
September 30, 2004	329,666	\$	3.00	\$	5.40	\$	2.40
December 31, 2004	23,333	\$	3.00	\$	16.20	\$	13.20
Total	353,832	\$	3.00	\$	6.11		

#### VALERA PHARMACEUTICALS, INC.

### NOTES TO FINANCIAL STATEMENTS (Continued)

The following table summarizes information about stock options outstanding and exercisable at December 31, 2006:

		Outstanding	Weighted	Exe	ercisable
		Weighted Average	Average		Weighted
Range of Exercise Price	Number	Remaining Contractual Life	Exercise Price	Number	Average Exercise Price
\$3.00	981,331	6.8 years	\$ 3.00	745,393	\$ 3.00
\$5.96-\$ 8.85	166,666	9.4 years	\$ 8.05	2,294	\$ 6.00
\$9.00-\$12.00	350,166	8.9 years	\$ 10.38	44,043	\$ 12.00
\$3.00-\$12.00	1,498,163	7.6 years	\$ 5.29	791,730	\$ 3.51

The following table summarizes information about stock options exercisable:

	December 31,				
	2006	2005	2004		
Exercisable Stock Options	791,730	605,032	334,164		
Weighted Average Exercise Price	\$ 3.51	\$ 3.11	\$ 3.00		

As of December 31, 2006, the Company had a total of 1,833,333 shares of its common stock for issuance pursuant to its Equity Plan. This included 1,498,163 of stock options outstanding, 51,762 of previously exercised stock options and 283,408 of stock options available for grant.

### Note 11. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting and the amount used for income tax purposes. The Company s deferred tax assets relate primarily to net operating loss carryforwards, research and development tax credits, and non-cash stock-based compensation. At December 31, 2006 and 2005, a valuation allowance was recorded to fully offset the net deferred tax asset. The change in the valuation allowance for the years ended December 31, 2006 and 2005 was approximately \$3.9 million and \$4.9 million, respectively. Significant components of the Company s deferred tax assets were as follows:

	Dec	ember 31,
	2006	2005
	(in t	housands)
Deferred tax assets:		
Net operating loss carryforwards	\$ 12,593	\$ 7,770
Research and development credits	1,604	1,423
Stock-based compensation		904
Amortization of stock-based compensation	192	126
Non-employee stock compensation	90	87
Other	811	1,049

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Total gross deferred tax assets	15,290	11,359
Deferred tax liabilities:		
Depreciation and amortization	197	134
Total gross deferred tax liabilities	197	134
Valuation allowance for deferred tax assets	(15,093)	(11,225)
Net deferred tax assets	\$	\$

#### VALERA PHARMACEUTICALS, INC.

#### NOTES TO FINANCIAL STATEMENTS (Continued)

As of December 31, 2006, the Company had federal net operating loss carryforwards of approximately \$32.5 million. The net operating loss carryforwards will expire at various dates beginning in 2022, if not utilized. The Company had research and development tax credit carry forwards at December 31, 2006, of approximately \$1.6 million, which will begin to expire in 2022. If an ownership change, as defined under Internal Revenue Code Section 382, occurs the use of these carry forwards may be subject to limitation.

(Benefit from) provision for income tax consists of:

	For the	For the Year December 31,		
	2006	2006 2005		
		in thousand	s)	
Federal	\$	\$ 20	\$	
State	(207)	55	(243)	
Total	\$ (207)	\$ 75	\$ (243)	

In 2006, the New Jersey Economic Development Authority approved the Company's application to sell New Jersey State income tax benefits under the New Jersey Technology Tax Transfer Program (the Program). During the fourth quarter of 2006, the Company recognized approximately \$193,000 from the sale of the State of New Jersey income tax benefits. The Program requires that the Company maintain certain employment levels in New Jersey and that the proceeds from the sale of the tax benefits be spent in New Jersey. The Company participated in this program in 2004 as well. During the fourth quarter of 2004, the Company recognized \$243,000 from the sale of State of New Jersey income tax benefits.

The Company has incurred net operating losses since inception. However, in 2005 the Company generated taxable income as a result of certain temporary and permanent differences between book income and taxable income. As a result, the Company recorded an alternative minimum tax provision of \$20,000 for federal purposes and \$55,000 for state purposes.

A reconciliation of the statutory tax rates and the effective tax rates for the periods ended:

	2006	December 31, 2005	2004
Statutory rate	(34)%	(34)%	(34)%
State and local income taxes (net of federal tax benefit)	(1)	(3)	(6)
Research and development tax credits	(1)	(11)	(2)
Alternative minimum tax		2	
Other permanent items	3	6	
Other	4		
Change in valuation allowance	28	46	42
	(1)%	6%	0%

#### Note 12. Net Loss Per Share

The Company computes its basic net loss per share by dividing net loss by the weighted-average number of shares of common stock outstanding. Diluted net loss per share of common stock (Diluted EPS) is computed by dividing net loss by the weighted-average number of shares of common stock and dilutive common equivalent shares then outstanding as long as such impact would not be anti-dilutive. All of the

common stock equivalent

### VALERA PHARMACEUTICALS, INC.

### NOTES TO FINANCIAL STATEMENTS (Continued)

shares for the years ended December 31, 2006, 2005 and 2004 have been excluded from the computation of diluted net loss per share as their effect would be anti-dilutive.

		Year Ended December 31, 2006 2005			2004				
	Net loss (Numerator)	Shares (Denominator)	Net loss (Numerator)	Shares (Denominator)	Net loss (Numerator)	Shares (Denominator)			
Basic net loss	\$ 13,939	13,580	\$ (1,344)	1,667	\$ (12,023)	1,667			
Deemed dividend					(5,861)				
Basic net loss per share factors	\$ 13,939	13,580	\$ (1,344)	1,667	\$ (17,884)	1,667			
Effect of preferred stock conversion									
Effect of dilutive stock options									
Diluted net loss per share factors	\$ 13,939	13,580	\$ (1,344)	1,667	\$ (17,884)	1,667			
Basic and diluted net loss per share	\$ (1.03)		\$ (0.81)		\$ (10.73)				
Note 13. Related Party Transactions									

In June 2004, David S. Tierney, the Company s President and CEO, loaned the Company \$200,000 at prime plus 1% above the UBS Margin Interest Rate. The loan was repaid in November 2004. Interest in the amount of \$2,000 is included in interest expense for 2004.

In August 2004, in connection with the sale of the Company s Series C Convertible Preferred Stock, the Company paid Sanders Morris Harris, Inc. a fee of \$280,000 for its services as placement agent. James C. Gale, the Chairman of the Company s board of directors, is a managing director of Sanders Morris Harris, Inc.

Sanders Morris Harris, Inc. and its affiliates own approximately 40% of the outstanding equity of BioPro Pharmaceutical, Inc. and over 90% of the outstanding equity of Alpex Pharma S.A., two companies with which the Company has agreements to distribute, develop and market its Vantas product. The Company received payments of approximately \$100,000 and \$300,000 during the years ended December 31, 2006 and 2005, respectively from BioPro. The Company made payments of approximately \$145,000 and \$400,000 during the years ended December 31, 2006 and 2005, respectively to Alpex.

On July 17, 2006, the Company entered into the Shareholders Agreement pursuant to which the Company received a 19.9% ownership in a newly created Dutch company called Spepharm Holding B.V. In accordance with the Shareholders Agreement, David S. Tierney, M.D., Valera s President and Chief Executive Officer and Mr. James Gale, the Company s chairman of the board of directors, were appointed as members of Spepharm s initial supervisory board. Additional investors in Spepharm include Life Sciences Opportunities Fund (Institutional) II, L.P and Life Sciences Opportunities Fund II, L.P. Both funds are funds managed by, and affiliates of, SMH, whose affiliates own approximately 37% of the outstanding common stock of the Company. Mr. Gale is a Managing Director of SMH and the investment manager of such funds that hold shares of Valera and has sole voting and dispositive power over such shares. SMH, along with a third party unaffiliated with the Company, have committed EUR 20,000,000 to the Spepharm venture.

On September 27, 2006, we entered into a License and Distribution Agreement with Spepharm Holding B.V. (Spepharm). Under the terms of the agreement, we will give Spepharm the exclusive licensing and

#### VALERA PHARMACEUTICALS, INC.

#### NOTES TO FINANCIAL STATEMENTS (Continued)

distributing rights to our products under the trademark Vantas<sup>®</sup> and Supprelin-LA in the European Union as well as Norway and Switzerland for a period of ten years, unless sooner terminated as provided by the agreement. Spepharm will pay us for our supply and Spepharm s distribution of the products under the agreement an aggregate amount equal to forty percent (40%) of Net Sales ( the Royalty Amount ) as defined by the agreement based on an established transfer price. In addition, following the end of each quarter, Spepharm will pay us an amount equal to the difference between (a) the aggregate Royalty Amount for such calendar quarter minus (b) the aggregate transfer prices paid by Spepharm during such calendar quarter.

#### Note 14. Defined Contribution Plan

The Company sponsors a 401(k) plan for eligible employees. The Company s contributions to the plan are discretionary and are 50% of the employee s contribution, not to exceed 5% of total compensation. Under the plan, each employee is fully vested in his or her deferred salary contributions. The Company s contributions vest over a three year period. The total Company 401(k) contributions amounted to approximately \$239,000, \$164,000 and \$55,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

#### Note 15. Acquisition of Product

On March 31, 2006, the Company completed its acquisition of the product rights associated with the product known as Valstar (valrubicin) in the United States and Valtaxin in Canada. As of December 31, 2006, the Company has an intangible asset of approximately \$446,000 associated with such product rights. The intangible asset was recorded at its original cost of \$525,000, less accumulated amortization of approximately \$79,000 as of December 31, 2006. Intangible assets are stated at cost, less accumulated amortization, and are amortized over their estimated useful lives using the straight-line method. The Company estimates that the useful life of the Valstar product rights is five years. The Company periodically reviews the original estimated useful lives of long-lived assets and makes adjustments when appropriate.

### Note 16. Selected Quarterly Financial Data (Unaudited)

	Quarter Ended					
	March 31,	June 30, (In thousands, ex		ember 30, r share amour		ember 31,
2006						
Total net revenue	\$ 5,532	\$ 6,220	\$	3,013	\$	3,201
Cost of product sales	1,461	1,653		883		1,110
Total operating expenses	7,818	9,246		8,002		7,987
(Loss) from operations	(2,286)	(3,026)		(4,989)		(4,786)
Provision for (benefit) from income taxes	10	10		(36)		(191)
Net (loss) attributable to common shareholders	(2,112)	(2,742)		(4,684)		(4,401)
Basic net (loss) attributable to common shareholders per common						
share	\$ (0.22)	\$ (0.18)	\$	(0.31)	\$	(0.29)
Diluted net (loss) attributable to common shareholders per common						
share	\$ (0.22)	\$ (0.18)	\$	(0.31)	\$	(0.29)

### VALERA PHARMACEUTICALS, INC.

### NOTES TO FINANCIAL STATEMENTS (Continued)

	March 31,	June 30,	Ended tember 30, t per share data)	Dec	ember 31,
2005					
Total net revenue	\$ 7,695	\$ 10,286	\$ 3,678	\$	5,173
Cost of product sales	1,023	2,951	809		1,183
Total operating expenses	5,972	8,777	6,805		6,596
Income (loss) from operations	1,723	1,509	(3,127)		(1,423)
Provision (benefit) for income taxes	160	140	(300)		75
Net income (loss) attributable to common shareholders	1,577	1,382	(2,808)		(1,495)
Basic net income (loss) attributable to common shareholders per					
common share	\$ 0.95	\$ 0.83	\$ (1.68)	\$	(0.90)
Diluted net income (loss) attributable to common shareholders per					
common share	\$ 0.14	\$ 0.12	\$ (1.68)	\$	(0.90)

### VALERA PHARMACEUTICALS, INC.

### VALUATION AND QUALIFYING ACCOUNTS SCHEDULE

### Schedule II

### (in thousands)

	Ba	alance at	Ch	arged to	Charged to			Ba	lance at
	Beş	ginning of	C	ost and	Other			1	End of
	J	Period	E	xpenses	Accounts	De	ductions	I	Period
For the year ended December 31, 2006:									
Allowance for Sales Returns and Adjustments	\$	339		1,083			1,279		143
For the year ended December 31, 2005:									
Allowance for Sales Returns and Adjustments	\$	344	\$	2,195		\$	2,200	\$	339
For the year ended December 31, 2004:									
Allowance for Sales Returns and Adjustments				398			54		344
For the year ended December 31, 2006:									
Allowance for Doubtful Accounts and Cash Discounts	\$	385	\$	840		\$	968	\$	257
For the year ended December 31, 2005:									
Allowance for Doubtful Accounts and Cash Discounts	\$	91	\$	557		\$	263	\$	385
For the year ended December 31, 2004:									
Allowance for Doubtful Accounts and Cash Discounts				91					91
For the year ended December 31, 2006:									
Tax Valuation Allowance	\$	11,225		3,868					15,093
For the year ended December 31, 2005:									
Tax Valuation Allowance	\$	10,646	\$	579				\$	11,225
For the year ended December 31, 2004:									
Tax Valuation Allowance		5,733		4,913					10,646
For the year ended December 31, 2006:									
Inventory Valuation Reserve	\$	1,198		140			160		1,178
For the year ended December 31, 2005:									
Inventory Valuation Reserve	\$	91	\$	1,083	\$ 138	\$	114	\$	1,198
For the year ended December 31, 2004:									
Inventory Valuation Reserve				91					91

### SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS

### AND MANAGEMENT OF INDEVUS

The following table sets forth certain information regarding the beneficial ownership of Indevus common stock and preferred stock as of March 1, 2007 for the following:

each of Indevus named executive officers;

each of Indevus directors;

all of Indevus directors and executive officers as a group; and

all persons known by Indevus to beneficially own more than 5% of Indevus common stock or preferred stock. Applicable percentage ownership is based on 56,200,285 shares of common stock outstanding as of March 1, 2007, together with applicable options for each stockholder. Beneficial ownership is determined in accordance with the rules of the SEC, based on factors including voting and investment power with respect to shares. Common stock subject to options currently exercisable, or exercisable within 60 days after March 1, 2007, are deemed outstanding for the purpose of computing the percentage ownership of the person holding those options, but are not deemed outstanding for computing the percentage ownership of any other person. For information relating to beneficial owners of greater than 5% of Indevus common stock who are not insiders, Indevus relies upon the reports filed by such persons or entities on Schedule 13G and Form 4. Unless otherwise noted, the address for each stockholder is 33 Hayden Avenue, Lexington, MA 02421-7966.

Beneficial Holder	Amount and Nature of Beneficial Ownership (1)	Percent of Outstanding Class of Stock Owned (20) Common
Glenn L. Cooper, M.D.	3,121,900(2)	5.3%
Thomas F. Farb	50,000(3)	*
Noah D. Beerman	422,501(4)	*
Mark S. Butler	1,229,775(5)	2.1%
Michael W. Rogers	1,548,618(6)	2.7%
Bobby W. Sandage, Jr., Ph.D.	1,473,184(7)	2.6%
John H. Tucker	339,470(8)	*
Andrew Ferrara		*
Michael E. Hanson	36,251(9)	*
Stephen C. McCluski	60,000(10)	*
Cheryl P. Morley	60,000(11)	*
Malcolm Morville, Ph.D.	153,001(12)	*
David B. Sharrock	221,002(13)	*
All directors and executive officers as a group	8,728,202(14)	13.6%

(13 persons)

Beneficial Holder	Amount and Nature of Beneficial Ownership (1)	Percent of Outstanding Class of Stock Owned (21) Common
Joseph Edelman	8,286,706(15)	13.6%
c/o First New York Securities, LLC 850 Third Avenue, 8th Floor		
New York, NY 10022		
OrbiMed Advisors LLC, OrbiMed Capital LLC,	4,388,500(16)	7.8%
Samuel D. Isaly 767 Third Avenue, 30th Floor		
New York, New York 10017		
Quogue Capital LLC	3,287,025(17)	5.7%
1285 Avenue of the Americas 35th Floor		
New York, New York 10019	2 427 265/19\	6%
Wayne P. Rothbaum Visium Asset Management, LLC	3,437,265(18) 2,981,417(19)	5.3%
Jacob Gottlieb 950 Third Avenue	2,501,117(15)	5.5 %
New York, NY 10022		
Wyeth	244,425 (20)	Preferred 100%
Five Giralda Farms		
Madison, New Jersey 07940		

\* Less than one percent.

(1) Beneficial ownership is defined in accordance with the rules of the Securities and Exchange Commission (S.E.C.) and generally means the power to vote and/or to dispose of the securities regardless of any economic interest therein. Share amounts include options which are exercisable within sixty (60) days.

(2) Includes (i) 266,900 shares, 71,900 of which are shares of restricted stock subject to vesting, transfer restrictions, forfeiture and acceleration, and (ii) 2,855,000 shares issuable upon exercise of options exercisable within 60 days, but excludes 97,500 shares issuable upon exercise of options held by Dr. Cooper s spouse, an employee of the Company, as to all of which shares Dr. Cooper disclaims beneficial ownership.

(3) Includes 50,000 shares, all of which are shares of restricted stock subject to vesting, transfer restrictions, forfeiture and acceleration.

(4) Includes (i) 31,099 shares, 28,800 of which are shares of restricted stock subject to vesting, transfer restrictions, forfeiture and acceleration, and (ii) 391,402 Shares issuable upon exercise of options exercisable within 60 day