INDEVUS PHARMACEUTICALS INC
Form S-4
January 29, 2007
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As filed with the Securities and Exchange Commission on January 29, 2007

Registration No. 333 -

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form S-4

REGISTRATION STATEMENT

UNDER THE SECURITIES ACT OF 1933

Indevus Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**04-3047911**
(State or other jurisdiction of organization)	**(Primary standard industrial classification code number)**	**(IRS employer identification number)**

33 Hayden Avenue

Lexington, MA 02421-7966

(781) 861-8444

(Address, including zip code, and telephone number, including area code, of registrants principal executive offices)

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

33 Hayden Avenue

Lexington, MA 02421-7966

(781) 861-8444

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Josef B. Volman, Esq.	**Marc S. Gerber, Esq.**	**Christopher S. Miller, Esq.**
Burns & Levinson LLP	**Skadden, Arps, Slate,**	**Pepper Hamilton LLP**
125 Summer Street	**Meagher & Flom LLP**	**400 Berwyn Park**
Boston, MA 02110-1624	**1440 New York Avenue, N.W.**	**899 Cassatt Road**
(617) 345-3000	**Washington, DC 20005-2111**	**Berwyn, PA 19312-1183**
	(202) 371-7000	**(610) 640-7800**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effectiveness of this Registration Statement and the effective time of the merger of Hayden Merger Sub, Inc., a direct, wholly-owned subsidiary of the Registrant, with and into Valera Pharmaceuticals, Inc. as described in the Agreement and Plan of Merger, dated as of December 11, 2006, included as *Annex A* to the joint proxy statement/prospectus forming a part of this Registration Statement.

If the securities being registered on this Form are being offered in connection with the formation of a holding company and there is compliance with General Instruction G, check the following box. ¨

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Unit	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Indevus Common Stock, $0.001 par value per share	38,675,756(1)	Not Applicable	$ 298,963,594(3)	$ 31,990(4)
Contingent Stock Rights Supprelin	16,435,388(2)	Not Applicable	Not Applicable	Not Applicable
Contingent Stock Rights Stent	16,435,388(2)	Not Applicable	Not Applicable	Not Applicable
Contingent Stock Rights Octreotide	16,435,388(2)	Not Applicable	Not Applicable	Not Applicable

(1) The aggregate number of shares of Indevus common stock being registered consists of an estimate of (a) 19,337,878 shares of Indevus common stock, which represents the maximum number of shares of Indevus common stock to be issued in exchange for shares of Valera Pharmaceuticals, Inc. (Valera) common stock in connection with the merger (assuming (x) 14,937,225 shares of Valera common stock outstanding, (y) 1,498,163 outstanding options to purchase Valera common stock and (z) a maximum exchange ratio of 1.1766) and (b) 19,337,878 shares of Indevus common stock, which represents the maximum aggregate number of shares of Indevus common stock that may be issued pursuant to conversion of the contingent stock rights issued to Valera stockholders in connection with the merger.

(2) The aggregate number of each class of contingent stock rights being registered consists of an estimate representing the maximum number of each class of contingent stock rights to be issued in exchange for shares of Valera common stock in connection with the merger.

(3) Estimated solely for the purpose of calculating the registration fee pursuant to Rules 457(f)(1) and 457(c) under the Securities Act. Based on the product of (a) $7.73, the average of the high and low sales prices of Valera common stock as reported on The Nasdaq Global Market on January 25, 2007, and (b) 38,675,756, the aggregate number of shares of Indevus common stock determined in accordance with footnote (1) above.

(4) Calculated pursuant to Section 6(b) of the Securities Act by multiplying the maximum aggregate offering price by 0.000107.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary joint proxy statement/prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission, of which this preliminary joint proxy statement/prospectus is a part, is effective. This preliminary joint proxy statement/prospectus is not an offer to sell and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY COPY SUBJECT TO COMPLETION, DATED JANUARY 29, 2007

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 for each share of Valera 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.

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 41.4% 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 Risk Factors 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.,	James C. Gale	David S. Tierney, M.D.
Chief Executive Officer and Chairman	Chairman of the Board	President and Chief Executive Officer
Indevus Pharmaceuticals, Inc.	Valera Pharmaceuticals, Inc.	Valera Pharmaceuticals, Inc.

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 [ ], 2007 and is first being mailed to

stockholders of Indevus and Valera on or about [ ], 2007.

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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 [ ] on [ ], 2007, at [ ]: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 seven 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 [ ], 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.

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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 seven 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,

Lexington, Massachusetts

, 2007

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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 the [ ] on [ ], 2007, at [ ]: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 **[ ]**, 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 41.4% 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 107 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

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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,

Cranbury, New Jersey

, 2007

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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 276 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 [ ], 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

60 E. 42nd Street, Suite 405

New York, NY 10165

T: 212-681-9600

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?

A4:

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

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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 111 and The Merger Agreement Closing and Effectiveness of the Merger beginning on page 112.

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 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.

See the section entitled The Merger Agreement Merger Consideration beginning on page 112.

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).

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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 113.

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 41.4% 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?

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. The transaction is targeted to close during the second calendar quarter of 2007, but 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 114.

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 at on , 2007, at :00 a.m., local time.

The Valera special meeting of stockholders will be held at the at on , 2007, at :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 [ ], 2007, will be entitled to notice of and to vote at the Indevus annual and special meeting.

Only holders of record of Valera common stock as of the close of business on [ ], 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?

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 107.

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 276.

Q25: Who can help answer my questions?

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

60 E. 42nd Street, Suite 405

New York, NY 10165

T: 212-681-9600

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.	Valera Pharmaceuticals, Inc.
33 Hayden Avenue	7 Clarke Drive
Lexington, MA 02421-7966	Cranbury, NJ 08512
(781) 861-8444	(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 276. We have included page references to direct you to a more complete description of the topics presented in this summary.

THE COMPANIES

Indevus (Page 136)

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 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® 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.

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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	Commercial Rights
SANCTURA	Overactive bladder	Marketed	U.S.[1]
SANCTURA XR	Overactive bladder	NDA[2] filed	Worldwide[3]
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

1 Licensed to Esprit.
2 NDA refers to a New Drug Application.
3 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	Commercial Rights
Sarafem	Premenstrual Dysphoric Disorder	Marketed	Worldwide[1]
Pagoclone	Stuttering	Phase III	Worldwide
Aminocandin	Systemic fungal infections	Phase I	Worldwide[2]

1 Licensed to Eli Lilly & Company
2 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

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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 138)

Overview

Valera Pharmaceuticals, Inc. 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 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 arrangement with Indevus and in January 2007, pursuant to the co-promotion arrangement, Valera and Indevus 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. 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, and nocturnal enuresis.

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 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. 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 Valera 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

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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 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	Delivery Method	Status
Vantas	Prostate Cancer	Urology	Implant	United States Commercial Sales
Supprelin®-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 ® (Valrubicin)	Bladder Cancer	Urology	Bladder Instillation	New Drug Application Approved
Endoureteral Stent	Maintenance of Ureteral Patency	Urology	Insertion	Pivotal Animal Study

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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.

The proposed merger will occur following approvals by Valera and Indevus stockholders of the applicable merger proposals and satisfaction or waiver of the other conditions to the merger. The merger is targeted to close during the second calendar quarter of 2007, but neither Indevus nor Valera can assure you when or if the merger will occur.

What Valera Stockholders Will Receive in the Merger (Page 112)

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.

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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 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.

What Holders of Valera Stock Options Will Receive in the Merger (Page 113)

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.

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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 after completion of 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).

Voting Agreements with Significant Valera Stockholders (Page 129)

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 36.5% and 4.9%, respectively, and approximately 41.4% 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.

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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 benefits to certain executive officers of Valera pursuant to existing agreements with Valera;
- 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; and

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.

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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 262 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 269 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 103)

Upon completion of the merger and subject to the approval of Indevus board of directors, it is anticipated that 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, will be invited to join Indevus board of directors and that Mr. Gale will accept a position on Indevus board. 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

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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 111)

Conditions to Completion of the Merger (Page 125)

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 120)

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.

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.

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Termination of the Merger Agreement (Page 126)

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 127)

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 107)

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 107)

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 107. 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.**

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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 235)

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 [ ].

Listing of Indevus Common Stock and Delisting of Valera Common Stock (Page 110)

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 [ ], 2007, the last full trading day prior to the date of this joint proxy statement/prospectus, Indevus common stock closed at $[ ] per share and Valera common stock closed at $[ ] 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 [ ], 2007, at [ ], local time, at [ ]. 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 seven 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;

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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 [ ], 2007. On that date, there were outstanding and entitled to vote [ ] shares of Indevus common stock, [ ] shares of Series B Preferred Stock and [ ] 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 [ ] 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 seven 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 [ ] 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 [ ]% of the total Indevus voting power as of such date.

The Valera Special Meeting (Page 75)

The Valera special meeting will be held on [ ], 2007, at [ ], local time, at [ ]. At the Valera special meeting, Valera stockholders will be asked to adopt the merger agreement

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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 [ ], 2007. On that date, there were outstanding and entitled to vote on all matters at the special meeting [ ] 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 [ ] shares of Valera common stock or approximately [ ]% 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).

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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. 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 276.

Consolidated Statements of Operations:

	Fiscal Years Ended September 30,				
	2006	2005	2004	2003	2002
	(Amounts in thousands except per share)				
Statement of Operations Data:					
Revenues:					
Product revenue	$ 26,738	$ 14,269	$ 9,740	$ 4,316	$ 3,439
Contract and license fees	23,714	19,067	8,986	929	968
Total revenues	50,452	33,336	18,726	5,245	4,407
Cost of product revenue	19,692	8,593	7,950	1,073	733
Research and development	43,203	30,597	23,303	24,466	13,614
Marketing, general and administrative	36,009	41,983	51,916	11,105	8,090
Loss from operations	(48,452)	(47,837)	(64,443)	(31,399)	(18,030)
Investment income	3,505	3,142	1,396	664	987
Interest expense	5,170	5,170	5,170	1,077	
Loss before income taxes	(50,554)	(50,047)	(68,212)	(31,812)	(17,586)
Provision for income taxes		(3,171)			
Net loss[1]	(50,554)	(53,218)	(68,212)	(31,812)	(17,586)
Preferred stock dividends	35	35	35	35	35
Net loss attributable to common stockholders	(50,589)	(53,253)	(68,247)	(31,847)	(17,621)
Loss per common share from operations- diluted	(1.02)	(1.13)	(1.43)	(0.68)	(0.38)
Net loss per common share-basic and diluted	$ (1.02)	$ (1.13)	$ (1.43)	$ (0.68)	$ (0.38)
Weighted average common shares-diluted	49,411	46,977	47,542	46,930	45,896

	September 30,				
	2006	2005	2004	2003	2002
	(Amounts in thousands)				
Balance Sheet Data:					
Working capital	$ 54,876	$ 79,233	$ 131,288	$ 73,866	$ 34,876
Total assets	92,307	112,531	173,838	90,071	43,931
Convertible Notes, long-term	72,000	72,000	72,000	72,000	
Total liabilities including deferred revenue	216,511	227,667	236,868	83,817	6,700
Accumulated deficit	(472,675)	(422,121)	(368,903)	(300,691)	(268,879)
Total stockholders equity (deficit)	(124,330)	(115,142)	(63,038)	6,241	37,218

(1) The Company adopted SFAS 123R on a modified prospective basis beginning in fiscal 2006.

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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 2001 through 2005 and from unaudited financial statements for the nine months ended September 30, 2006 and 2005. In the opinion of Valera s 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 nine months ended September 30, 2006 and 2005. Results for interim periods should not be considered indicative of results for any other periods or for the year.

The information is only a summary. You should read it along with Valera s historical audited and unaudited financial statements and related notes beginning on page 187 and the section entitled Valera Management s Discussion and Analysis of Financial Condition and Results of Operations of Valera beginning on page 165.

Statements of Operations:

	Nine months ended September 30, 2006	Nine months ended September 30, 2005	Year Ended December 31, 2005	2004	2003	2002	2001
			(in thousands, except per share amounts)				
Statements of Operations:							
Net product sales	$ 14,649	$ 21,633	$ 26,798	$ 5,511	$ 7	$ 15	$ 8
Licensing revenue	116	26	34	135			
Total net revenue	14,765	21,659	26,832	5,646	7	15	8
Operating costs and expenses							
Cost of product sales	3,997	4,783	5,966	608			
Research and development	5,714	4,411	5,930	6,376	5,230	4,320	2,616
Selling and marketing	9,705	8,232	10,754	5,025	509	270	
General and administrative	5,598	4,128	5,500	5,897	1,838	1,324	1,522
Amortization of intangible assets	52						
Total operating expenses	25,066	21,554	28,150	17,906	7,577	5,914	4,138
(Loss) income from operations	(10,301)	105	(1,318)	(12,260)	(7,570)	(5,899)	(4,130)
Interest income (expense), net	747	46	49	(6)	13	16	(30)
(Loss) income before income taxes	(9,554)	151	(1,269)	(12,266)	(7,557)	(5,883)	(4,160)
(Benefit from) provision for income taxes	(16)		75	(243)			
Net (loss) income	(9,538)	151	(1,344)	(12,023)	(7,557)	(5,883)	(4,160)
Deemed dividend				(5,861)	(1,139)		
Net (loss) income attributable to common stockholders	$ (9,538)	$ 151	$ (1,344)	$ (17,884)	$ (8,696)	$ (5,883)	$ (4,160)
Basic net (loss) income attributable to common stockholders per share	$ (0.73)	$ 0.09	$ (0.81)	$ (10.73)	$ (5.22)	$ (3.53)	$ (8.06)

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	Nine months ended September 30, 2006	Nine months ended September 30, 2005	Year Ended December 31, 2005	2004	2003	2002	2001
			(in thousands, except per share amounts)				
Diluted net (loss) income attributable to common stockholders per share	$ (0.73)	$ 0.01	$ (0.81)	$ (10.73)	$ (5.22)	$ (3.53)	$ (8.06)
Weighted average shares outstanding basic	13,123	1,667	1,667	1,667	1,667	1,667	516
Weighted average shares outstanding diluted	13,123	11,358	1,667	1,667	1,667	1,667	516

	As of September 30, 2006	2005	As of December 31, 2005	2004	2003	2002	2001
			(in thousands)				
Balance Sheet Data:							
Cash and cash equivalents	$ 15,891	$ 2,569	$ 2,340	$ 5,053	$ 5,241	$ 640	$ 6,620
Working capital (Deficit)	22,036	6,090	2,845	8,306	4,585	(403)	5,657
Total assets	35,749	16,377	16,532	13,667	6,664	1,296	7,172
Long-term liabilities	315	307	300	17	32	66	123
Convertible preferred stock		39,925	39,925	39,925	20,469	6,603	6,603
Total stockholders equity (deficit)	29,876	(29,719)	(31,593)	(29,887)	(15,158)	(6,464)	(582)

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Selected Quarterly Financial Data (Unaudited) of Valera:

	2006 Quarters Ended		
	March 31,	June 30,	September 30,
	(In thousands, except per share amounts)		
Total net revenue	$ 5,532	$ 6,220	$ 3,013
Cost of product sales	1,461	1,653	883
Total operating expenses	7,818	9,246	8,002
Loss from operations	(2,286)	(3,026)	(4,989)
Provision for (benefit from) income taxes	10	10	(36)
Net loss attributable to common shareholders	(2,112)	(2,742)	(4,684)
Basic net loss attributable to common shareholders per common share	$ (0.22)	$ (0.18)	$ (0.31)
Diluted net loss attributable to common shareholders per common share	$ (0.22)	$ (0.18)	$ (0.31)

	2005 Quarters Ended			
	March 31,	June 30,	September 30,	December 31,
	(In thousands, except per share amounts)			
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)

	2004 Quarters Ended			
	March 31,	June 30,	September 30,	December 31,
	(In thousands, except per share data)			
Total net revenue	$		$ 135	$ 5,511
Cost of product sales				608
Total operating expenses	2,018	3,540	3,704	8,644
Loss from operations	(2,018)	(3,540)	(3,569)	(3,133)
Benefit from income taxes				244
Net loss	(2,016)	(3,545)	(3,568)	(2,894)
Net loss attributable to common shareholders	(2,016)	(3,641)	(9,333)	(2,894)
Basic and diluted net loss attributable to common shareholders per common share	$ (1.21)	$ (2.18)	$ (5.60)	$ (1.74)

Diluted EPS is identical to basic EPS since common stock equivalent shares are excluded from the calculation, as their effect is anti-dilutive in all periods presented.

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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 statement of operations for the twelve months ended September 30, 2006 for Valera and for the year ended September 30, 2006 for Indevus and the unaudited pro forma combined consolidated balance sheet as of September 30, 2006 is based on the historical balance sheets of Indevus and Valera as of that date. The unaudited pro forma combined consolidated statement of operations 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 September 30, 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 information purposes only. The unaudited pro forma combined consolidated financial data are not necessarily indicative of the financial position or operating results that would have been achieved had the merger been consummated as of the dates indicated, 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.

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UNAUDITED PRO FORMA COMBINED CONSOLIDATED BALANCE SHEET

(Amounts in thousands except share data)

	As of September 30, 2006			
	Historical		Pro forma	
	Indevus	Valera	Adjustments	Combined
ASSETS				
Current assets:				
Cash and cash equivalents	$ 70,169	$ 15,891	$	$ 86,060
Marketable securities	5,956	2,982		8,938
Accounts receivable, net	2,851	2,311		5,162
Inventories	1,628	5,569	950(C)	8,147
Prepaid and other current assets	2,598	841		3,439
Total current assets	83,202	27,594	950	111,746
Property and equipment, net	880	7,513	405(C)	8,798
Insurance claim receivable	1,258			1,258
Prepaid debt issuance costs	1,183			1,183
Inventories		3,293		3,293
Intangible assets,		473	31,577(A)	32,050
Other assets	2,491	169	1,200(C)	3,860
Goodwill			7,277(E)	7,277
Total assets	$ 92,307	$ 35,749	$ 41,409	$ 169,465
LIABILITIES				
Current liabilities:				
Accounts payable	$ 2,917	$ 3,233	$	$ 6,150
Accrued expenses	11,026	2,314	11,806(F),(G)	25,146
Accrued interest	950			950
Deferred revenue	13,433			13,433
Capital lease obligations current		11		11
Total current liabilities	28,326	5,558	11,806	45,690
Convertible notes	72,000			72,000
Deferred revenue	114,041	300	(200)(C)	114,141
Capital lease obligations long term		15		15
Other	2,144		150(C)	2,294
Minority interest	126			126
STOCKHOLDERS DEFICIT				
Convertible preferred stock				
Series B	3,000			3,000
Series C	500			500
Common stock, $.001 par value	15		(15)(H)	56
			17(H)	17
Additional paid-in-capital	344,789	79,060	(79,060)(H)	344,789
			103,463(H)	103,463
			4,164(H)	4,164
Accumulated deficit	(472,675)	(49,199)	49,199(H)	(472,675)
			(40,000)(I)	(40,000)
			(6,894)(F),(G)	(6,894)
			(1,220)(J)	(1,220)

Total stockholders deficit	(124,330)	29,876	29,653	(64,801)
Total liabilities and stockholders deficit	$ 92,307	$ 35,749	$ 41,409	$ 169,465

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UNAUDITED PRO FORMA COMBINED CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in thousands except share data)

	For the year ended September 30, 2006			
	Historical		Pro forma	
	Indevus	Valera	Adjustments	Combined
Revenues:				
Product revenue	$ 26,738	$ 19,814	$	$ 46,552
Contract and license fees	23,714	124		23,838
Total revenues	50,452	19,938		70,390
Costs and Expenses:				
Cost of product revenue	19,692	5,180	3,078(B),(D)	27,950
Research and development	43,203	7,233		50,436
Marketing, general and administrative	36,009	19,249		55,258
Total costs and expenses	98,904	31,662	3,078	133,644
Loss from operations	(48,452)	(11,724)	(3,078)	(63,254)
Investment income	3,505			3,505
Interest expense	(5,170)	750		(4,420)
Minority interest and other	(437)			(437)
Loss before income taxes	(50,554)	(10,974)	(3,078)	(64,606)
Provision for income taxes		59	(K)	59
Net loss	$ (50,554)	$ (11,033)	$ (3,078)	$ (64,665)
Net loss per common share, basic and diluted	$ (1.02)	$ (1.08)	$ (0.19)	$ (0.98)
Weighted average common shares outstanding, basic and diluted	49,411	10,236	16,587(L)	65,998

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 $111.3 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 1.0669 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 $7.26, which incorporates the average trading price of Indevus common stock for the 25 trading days ending five trading days prior to January 18, 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 $6.49 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 January 18, 2007. The merger also provides the Valera option holders the right to receive shares of Indevus stock as consideration for the cancellation 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 654,000 shares of Indevus common stock, at a fair value of $6.37, based on the closing price of Indevus common stock on January 18, 2007, which aggregates $4.2 million, of which $2.9 million is additional purchase price and $1.2 million is non-cash compensation expense

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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 (15.9 million shares at $6.49 per share)	$ 103,480
Fair value of Indevus common stock to be issued as consideration for Cancellation of outstanding Valera stock options	2,943
Estimated Indevus transaction costs	4,912
Total preliminary purchase price	$ 111,335

Although the Valera stockholders will also receive CSRs, and the option holders 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 $58.7 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 $93.4 million to $114.1 million, at an assumed fair value of $6.49.

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 the Company 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	$ 32,008
In-process research and development	40,000
Identifiable intangible assets	32,050
Goodwill	7,277
Total preliminary consideration	$ 111,335

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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, deferred revenue and unfavorable lease obligations.

D. To record additional depreciation expense and cost of sales of $140,000 and $1 million, respectively, resulting from the fixed asset and inventory fair value adjustments.

E. To record goodwill related to the merger of $7.3 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 $4.6 million of Indevus transaction costs, included as a component of total purchase price, and $4.5 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 16.6 million shares of Indevus $0.001 par value common stock with an estimated value of $107.6 million in exchange for all common stock of Valera, including an adjustment of $4.2 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 $4.2 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 effecting connection with the merger.

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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 Data and related notes thereto beginning on page 26. 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, 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, 2005 and the unaudited interim financial statements for the nine months ended September 30, 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)
As of and for the period ended September 30, 2006 (1)				
Net income (loss)				
Basic	$ (1.02)	$ (1.08)	$ (0.98)	$ (1.05)
Diluted	$ (1.02)	$ (1.08)	$ (0.98)	$ (1.05)
Book value (2)	$ (2.22)	$ 2.00	$ (0.98)	$ (1.05)

(1) For Indevus, as of and for the twelve month period ended September 30, 2006. For Valera, as of and for the twelve month period ended September 30, 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 1.0669 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.

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COMPARATIVE STOCK PRICES AND DIVIDENDS

Indevus common stock is quoted on The Nasdaq Global Market under the symbol IDEV. Valera common stock is quoted on The Nasdaq Global Market under the symbol VLRX. Valera completed its initial public offering of common stock on February 7, 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 January 26, 2007)	7.14	6.18
Valera		
Fiscal Year 2006		
First Quarter (commencing February 7, 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 January 26, 2007)	8.20	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 pro forma 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 January 25, 2007, the last practicable trading day before the date of this joint proxy statement/prospectus. The calculation for the Valera pro forma equivalent share price does not include CSRs.

	Indevus	Valera	Valera Pro Forma Equivalent
December 11, 2006	$ 7.86	$ 5.41	$ 7.75
January 26, 2007	$ 6.25	$ 7.73	$ 7.35

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

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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 276.

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.

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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 greater than $7.75 per share of Valera common stock.

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 actually receive stock certificates evidencing the Indevus common stock. Until stock certificates are received, 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

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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

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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

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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 $4.6 million in transactional expenses, approximately $3.1 million of which are not contingent on the completion of the merger. Valera currently expects to incur approximately $3.0 million in transactional expenses, approximately $1.8 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 127.

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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 26.

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 benefits to certain executive officers of Valera pursuant to existing agreements with Valera;
- 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; and
- 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.

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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 110. 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 276, the Risks Relating to Valera described below and the section entitled Information about Valera beginning on page 138.

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 120 of this joint proxy statement/prospectus, The Merger Agreement Termination of the Merger Agreement beginning on page 126, and The Merger Agreement Termination Fees; Reimbursement of Expenses beginning on page 127. 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.

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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

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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 to revert to Indevus, then the marketing of SANCTURA XR may be adversely affected and if efforts to develop and market 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 and 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

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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 or have not received FDA approval, even after promising results in earlier trials. For example, while there have been three Phase II clinical trials of pagoclone that demonstrated 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.

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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 for Medicare beneficiaries and are likely to be lower than it might otherwise obtain. Non-Medicare third-party 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 amounts will not reduce the demand for, or the price of, its drug products. Any reduction in demand would adversely affect its business. If 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

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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

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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;

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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 September 30, 2006 it had an accumulated deficit of approximately $472,700,000.

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

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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
- 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

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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.

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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

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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.

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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 September 30, 2006, Indevus had 56,040,456 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

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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 September 30, 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;
- 12,132,778 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
- 2,414,618 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 September 30, 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;

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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 other regulatory authorities, and 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 its 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 only source of revenue will be sales of Vantas. If Valera is unable to successfully expand the commercialization of Vantas, Valera may be required to cease or reduce its 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 September 30, 2006 Valera has incurred annual operating losses, and, as of September 30, 2006, Valera has an accumulated deficit of approximately $49.2 million. The majority of this deficit is attributable to research and development expenditures of $31.3 million, primarily for Vantas. 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 the initial public offering of its common stock, 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, which are necessary for the manufacture of its Hydron implants. 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 that use Hydron Technology.

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. Valera 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 it 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

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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 its 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 its 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 its sales for the third quarter of 2005 and may have an adverse impact on Valera s sales of Vantas in the future. Further interruptions in Valera s manufacturing process for Vantas or its product candidates may have an adverse impact on Valera s sales of Vantas and the development of its product candidates in the future.

Valera has experienced two separate disruptions in its manufacturing of Vantas due to issues caused by its 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 its 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 2005 sales were 1,747 units, which was less than its 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 its ability to sell Vantas in the future. In fact, sales of Vantas were slower in the third quarter of 2006 as compared to the other quarters of 2006, in part because of the disruption experience of 2005 and the resulting lack of implanted patients that returned for re-implants 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 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

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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 the countries of the European Union, the pricing of prescription drugs is subject to government control. If Valera s products are or become subject to government regulation that limits or prohibits payment for products, or that subject the price of 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® (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 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 these 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 Valera will be able to successfully implement the 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, Valera s competitors may introduce 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 the problem, 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, its 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.

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

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with other parties, including collaborators, to perform these services for it. Valera may not be able to negotiate favorable distribution or marketing arrangements. To the extent that Valera enters into co-promotion or other arrangements, any revenues Valera receives will depend upon the efforts of third parties which may not be successful and are only partially within its control. Valera will be competing with companies that have experienced and well-funded marketing and sales operations. The failure to adequately sell and distribute Vantas or Valera s 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 September 30, 2006, the cumulative amount of royalty expense incurred by Valera as a result of sales of Vantas was approximately $2.4 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

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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., 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 Valera. Valera has entered into an employment agreement with Dr. Tierney. In addition, Valera has entered into change of control agreements with each of its other executive officers. 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 its 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 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

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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 endocrine pharmaceuticals in late-stage development for the treatment of central precocious puberty and acromegaly, Valera s competitors currently include TAP Pharmaceutical Products Lupron Depot-PED, 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. 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 its business. In addition, there may be product candidates of which Valera is not aware at an earlier stage of development that may compete with Valera s 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;

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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 effect risk compared to the therapeutic benefit may not be acceptable when used for the intended indications for the product candidate. 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 Valera s 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;

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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