INTERNEURON PHARMACEUTICALS INC Form 424B1 March 07, 2002

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PROSPECTUS

3,175,000 Shares

Interneuron Pharmaceuticals, Inc. One Ledgemont Center 99 Hayden Avenue Lexington, MA 02421-7966 (781) 861-8444

Common Stock

This prospectus relates to the public resale, from time to time, of up to 3,175,000 shares of our Common Stock, par value \$.001 per share (the "Shares"), by certain Selling Stockholders listed on page 12 of this prospectus under the section entitled "Selling Stockholders". We will not receive any proceeds from the sale of the Shares by the Selling Stockholders covered by this prospectus.

Our Common Stock is listed on The Nasdaq National Market under the symbol "IPIC." On February 27, 2002, the closing sale price for our Common Stock was \$8.29 per share.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. YOU SHOULD CAREFULLY CONSIDER THE "RISK FACTORS" BEGINNING ON PAGE 4 OF THIS PROSPECTUS.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is March 7, 2002.

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SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

Statements in this prospectus, and the documents incorporated by reference into this prospectus, that are not statements or descriptions of historical facts are "forward-looking" statements under Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Private Securities Litigation Reform Act of 1995 and are subject to numerous risks and uncertainties. These and other forward-looking statements made by us in reports that we file with the Securities and Exchange Commission, press releases, and public statements of our officers, corporate spokespersons or our representatives are based on a number of assumptions and relate to, without limitation: our ability to successfully develop, obtain regulatory approval for and commercialize any products; our ability to enter into corporate collaborations or to obtain sufficient additional capital to fund operations; and the Redux(TM)-related litigation. The words "believe," "expect," "anticipate," "intend," "plan," "estimate" or other expressions which predict or indicate future events and trends and do not relate to historical matters identify forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements as they involve risks and uncertainties and such forward-looking statements may turn out to be wrong. Actual results could differ materially from those currently anticipated due to a number of factors, including those set forth under "Risk Factors" and elsewhere in, or incorporated by reference into, this prospectus. These factors include, but are not limited to: uncertainties relating to clinical trials, regulatory approval and commercialization of our products; the early stage of products under development; need for additional funds and corporate partners;

history of operating losses and expectation of future losses; product liability and insurance uncertainties; risks relating to the Redux-related litigation; dependence on third parties for manufacturing and marketing; competition; risks associated with contractual arrangements; limited patents and proprietary rights; and other risks. The forward-looking statements represent our judgment and expectations as of the date of this prospectus. We assume no obligation to update any such forward-looking statements. See "Risk Factors."

THE COMPANY

Interneuron Pharmaceuticals, Inc. is a biopharmaceutical company engaged in the development and commercialization of a diversified portfolio of product candidates, including multiple compounds in late stage clinical development. We are currently developing or have certain rights to six compounds. The names of these compounds and their intended uses are as follows: pagoclone for the treatment of panic and generalized anxiety disorders, trospium for the treatment of overactive bladder, IP 501 for the treatment of cirrhosis of the liver, citicoline for the treatment of strokes caused by blood clots, PRO 2000 for the prevention of infection by the human immunodeficiency virus and other sexually transmitted pathogens, or disease causing agents, and dersalazine for the treatment of inflammatory bowel disease.

We are a Delaware corporation and were incorporated in March 1990. Our principal executive offices are located at One Ledgemont Center, 99 Hayden Avenue, Lexington, Massachusetts 02421-7966, and our telephone number is (781) 861-8444.

In this prospectus, the terms "Interneuron", "we", "us" and "our" includes Interneuron Pharmaceuticals, Inc. and its subsisdiaries.

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RISK FACTORS

The following factors should be reviewed carefully, in conjunction with the other information contained in this prospectus. These factors, among others, could cause actual results to differ materially from those currently anticipated and contained in forward-looking statements made in this prospectus and presented elsewhere by Company management from time to time. See "Special Note Regarding Forward Looking Statements."

Our products are early stage and may not be successful or achieve market acceptance.

We currently have rights to six compounds which are in various stages of testing and have not been approved by the United States Food and Drug Administration. The four core compounds which are the focus of our development program are trospium, which is in Phase III clinical trials, pagoclone, which is in Phase III clinical trials for panic disorder and Phase II clinical trials for generalized anxiety disorder, PRO 2000 which is in Phase II clinical trials, and dersalazine, which is in Phase I clinical trials. The products we are developing 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. We are unable to predict whether any of our products will receive regulatory clearances or 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 or procedures are long and uncertain. Even if our products receive regulatory clearance, our products may not achieve or maintain market acceptance.

We rely on the favorable outcome of clinical trials of our products.

Before obtaining regulatory approval for the commercial sale of any of the pharmaceutical products we are developing, we or our licensees must demonstrate that the product is safe and efficacious for use in each target indication. The process of obtaining U.S. Food and Drug Administration and other regulatory approval is lengthy and expensive. If clinical trials do not demonstrate the safety and efficacy of certain products under development, we 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 we are 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 could be considerable and the failure to obtain, or delays in obtaining regulatory approval could have a significant negative effect on our business performance and financial results. Even if pre-market approval of a product is obtained, the FDA is authorized to impose post-marketing requirements. A number of companies in the pharmaceutical industry, including our company, have suffered significant setbacks in advanced clinical trials or have not received FDA approval, even after promising results in earlier trials. In 1998, we withdrew our New Drug Application for citicoline, a compound designed to treat ischemic stroke, after the failure to meet our primary objective in a small Phase III clinical study.

We will depend on Pfizer to develop, manufacture and market pagoclone.

Under our agreement with Pfizer Inc., we licensed to Pfizer exclusive, worldwide rights to develop and commercialize pagoclone, a compound under development for the treatment of panic and generalized anxiety disorders. This agreement terminates upon the later to occur of 10 years from the first commercial sale of the compound or when certain patents on pagoclone expire, which vary on a country by country basis, or the agreement may also be terminated earlier by Pfizer when Pfizer stops researching, developing or selling pagoclone or on six months notice to us. To date, we have received \$16,750,000 under the agreement, and we will be entitled to receive up to an additional \$62,000,000 in payments contingent upon the achievement of clinical and regulatory milestones. Pfizer will also pay us royalties on net sales if pagoclone is commercialized. Under our agreement with Pfizer, we do not have control over the development or commercialization of pagoclone. We would be materially adversely affected if Pfizer does not successfully develop pagoclone. We will be dependent on Pfizer to manufacture pagoclone under current Good Manufacturing Practices regulations. We will also be dependent on Pfizer for the marketing and distribution of pagoclone.

We could be materially harmed if our agreements were terminated.

Our 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 our agreements require us to diligently

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pursue development of the underlying product or risk loss of the license or incur penalties. Depending upon the importance to us of the product that is subject to any such agreement, this could materially adversely affect our business. Termination of our agreement with Pfizer related to Pfizer's development and commercialization of our compound pagoclone, our agreement with Aventis S.A., under which we license our compound pagoclone, or our agreement with Madaus A.G., under which we license our compound trospium, could

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substantially reduce the likelihood of successful commercialization of our products which would materially harm us. The agreements with Aventis or Madaus may be terminated by either of them if we are in material breach of either agreement or if we become insolvent or file bankruptcy.

We will rely on third parties to commercialize and manufacture our products.

We require substantial additional funds to complete development of our products and anticipate forming partnerships to manufacture and market our products. We seek corporate partners to fund development and commercialization of our products. We may not be successful in finding corporate partners or obtaining other financing and, if obtained, the terms of any such arrangements may not be favorable to us. If we are not able to obtain any such corporate partners or financing, development of our products could be delayed or curtailed, which could materially adversely affect our operations and financial condition.

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

We currently contract with third parties for all of our manufacturing needs and do not manufacture any of our own products or product candidates. Typically purchase orders for supplies of clinical compounds are filled on an as-requested basis and are not the subject of long-term contracts. As a result, we cannot be certain that manufacturing sources will continue to be available or that we can continue to out-source the manufacturing of any of our products or product candidates on reasonable terms or at all. Any manufacturing facilities for any of our compounds are subject to U.S. Food and Drug Administration inspection both before and after New Drug Application approval to determine compliance with current Good Manufacturing Practices requirements. Facilities used to produce our compounds may not have complied, or may not be able to maintain compliance, with current Good Manufacturing Practices. The current Good Manufacturing Practices regulations are complex and failure to be in compliance could lead to non-approval or delayed approval of the New Drug Applications. This 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.

Our failure to acquire and develop additional product candidates will impair our ability to grow.

Unlike most pharmaceutical companies, we generally do not conduct our own internal research to discover new drug compounds. Instead, we depend on the licensing of compounds from others for development. Therefore, in order to continue to grow, we must continue to acquire and develop additional compounds. The success of this strategy depends upon our ability to continue to identify, select and acquire compounds that meet the criteria we have established. Identifying suitable compounds is a lengthy and complex process. In addition, we compete with other companies with substantially greater financial, marketing and sales resources for the acquisition of compounds. We may not be able to acquire the rights to additional compounds on terms we find acceptable or at all.

We need additional funds in the future.

We continue to expend substantial funds for product development activities, research and development, pre-clinical and clinical testing, operating expenses, regulatory approval, licensing and other strategic relationships

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and manufacturing. In fiscal 2001, we used approximately \$2,000,000 to fund operating activities. We expect the cash used in operating activities in fiscal 2002 to increase significantly as we continue to fund our development activities. Accordingly, we may require additional funds after fiscal 2002. We may seek additional funds during or after fiscal 2002 through corporate collaborations or public or private equity or debt financings. If we raise 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, however, that additional financing will be available on terms acceptable to us or at all. If we sell securities in a private offering, we may have to sell such shares at a discount from the market price of our stock which could have a depressive effect on our stock price. In addition, future resales of shares in the public market sold in a private offering could negatively affect our stock price.

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

- . the progress of research and development programs;
- . costs and results of pre-clinical and clinical testing;
- . the timing and cost of obtaining regulatory approvals;
- . whether we are successful in either in-licensing or out-licensing products;
- . whether Pfizer is successful in developing pagoclone and the timing of any milestone payments related to our agreement with Pfizer;
- . whether we are successful in defending against our Redux product liability litigation; and
- . the timing and extent of reimbursement from insurers.

As a result of the uncertainties and costs associated with business development activities, market conditions, the Redux-related litigation and other factors generally affecting our ability to raise additional funds, we 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 us. We may have to curtail our operations or delay development of our products.

We have a history of losses and expect losses to continue.

Other than in fiscal 2000, we have incurred substantial net losses over the past five fiscal years including net losses of \$55,000,000, \$70,000,000, \$38,000,000, and \$1,500,000 for fiscal years 1997, 1998, 1999 and 2001, respectively. Through September 30, 2001, we had accumulated net losses since inception of approximately \$251,000,000. We expect to have losses and use cash in operating activities for the foreseeable future. We will be required to conduct significant development and clinical testing activities for the products we are developing and these activities are expected to result in continued operating losses and use of cash for the foreseeable future. We

cannot predict the extent of future losses or the time required to achieve profitability. In addition, payments made by us in connection with product liability litigation would result in significant charges to operations and would materially adversely affect our results of operations and financial condition.

We may not be profitable in the future.

We may never achieve or sustain profitability in the future. Our cumulative revenues received through September 30, 2001 were approximately \$144,000,000, of which approximately \$73,000,000 was derived from Redux, which was withdrawn from the market in September 1997. We expect 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.

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We have product liability exposure and insurance uncertainties related to our products.

The use of products in clinical trials and the marketing of products may expose us to substantial product liability claims and adverse publicity. Certain of our agreements require us to obtain specified levels of insurance coverage, naming the other party as an additional insured. We currently maintain product liability insurance in the amount of \$20,000,000. We may not be able to maintain or obtain insurance coverage, or to obtain insurance in amounts sufficient to protect us or other named parties against liability, at a reasonable cost, or at all. In addition, any insurance obtained may not cover any particular liability claim. One of our insurers is in liquidation proceedings and may not be able to reimburse us under our policy. Another insurer has claimed it is entitled to recover twenty million dollars that it has paid to us under our policy. We cannot predict the extent to which the Redux-related litigation may affect our ability to obtain sufficient product liability insurance for other products at costs acceptable to us. We have indemnified certain licensors and licensees and may be required to indemnify additional licensors or licensees against product liability claims incurred by them as a result of products we develop or market. If uninsured or insufficiently insured product liability claims arise, or if a successful indemnification claim was made against us, our business and financial condition could be materially adversely affected.

The outcome of the Redux litigation could materially harm us.

On September 15, 1997, we announced a market withdrawal of our first prescription product, the weight loss medication Redux (dexfenfluramine hydrochloride capsules) C-IV, which had been launched by American Home Products Corporation, our licensee, in June 1996. Following the withdrawal, we have been named, together with other pharmaceutical companies, as a defendant in approximately 3,200 product liability legal actions, many of which purport to be class actions, in federal and state courts involving the use of Redux and other weight loss drugs. In related litigation, we have been sued by one of our insurers, alleging that we compromised its subrogation rights by entering into an agreement with American Home Products Corporation providing us with certain indemnification and release of claims related to Redux.

The existence of such litigation may continue to materially adversely affect our business, including our ability to obtain sufficient financing to fund operations. In addition, although we are 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 us, our business, financial condition and results of operations could be materially adversely affected. In addition, the costs and uncertainties associated with these legal actions have had, and may continue to have, an adverse effect on the market price of our Common Stock and on our 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 us, or at all, any or all of which may materially adversely affect our business, financial condition and results of operations. The American Home Products Indemnity and Release Agreement provides for indemnification of Redux-related claims brought by plaintiffs who have elected not to stay in American Home Products' 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. However, uninsured or insufficiently insured Redux-related claims or Redux-related claims which are not covered by the American Home Products Indemnity and Release Agreement may arise. Any such claims, if successful, could have a material adverse effect on our business, results of operations and financial condition.

We have limited patent protection on our products.

Our compounds are currently covered by approximately 200 registered patents and patent applications. The issued patents expire between the years 2003 and 2017. Our future success will depend to a significant extent on our ability to:

. obtain and enforce patent protection on our products and technologies;

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- . maintain trade secrets; and
- . operate and commercialize products without infringing on the patents or proprietary rights of others.

Our patents may not afford any competitive advantages and may be challenged or circumvented by third parties. Further, patents may not issue on pending patent applications. 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.

Our license to trospium, a compound under development for treatment of overactive bladder, does not include any patents expected to be used in commercializing the product.

Our licensed U.S. patent covering the administration of citicoline to treat patients afflicted with conditions associated with the inadequate release of brain acetylcholine expires in 2003. This patent, along with the additional patents issued to us relating to citicoline, may not afford protection against competitors of citicoline to treat ischemic stroke.

Our business may be materially adversely affected if we fail 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 our patents;
- . to determine the scope and validity of the patent rights of others; or
- . in response to legal action against us 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 outcome of any litigation is highly uncertain. Any litigation may also result in significant use of management and financial resources.

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

We may depend on market exclusivity for trospium and other products.

Assuming regulatory approvals are obtained, our ability to commercialize successfully certain drugs, including trospium, may depend on the availability of market exclusivity or patent extension under the Drug Price Competition and Patent Term Restoration Act of 1984, which is commonly known as the Waxman-Hatch Act, which provides protections for certain new products. Under the Waxman-Hatch Act, a company which does not have a patent on a compound may obtain five years of market exclusivity if the United States Food and Drug Administration determines such compound to be a new chemical entity. If we receive favorable treatment under the Waxman-Hatch Act for trospium, we can obtain market exclusively for a period of five years from the date of United States Food and Drug Administration approval. The marketing of trospium could be materially adversely affected if marketing exclusivity is not available to us.

Our products may be unable to compete successfully with other products.

Competition from other pharmaceutical companies is intense and is expected to increase. We are aware of existing products and of products under development by our competitors that address diseases we are targeting

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and competitors have developed or are developing products or technologies that are, or may compete with our products.

- . Pagoclone would compete with a number of drugs available and under development to treat anxiety or panic disorders, including serotonergic drugs such as BuSpar, Paxil, Zoloft, Prozac and Effexor and benzodiazepines such as Valium and Xanax.
- . Trospium would compete with other therapies for overactive bladder, including anticholinergics, such as Detrol and Detrol LA and Ditropan and Ditropan XL. In addition, we are aware of other companies evaluating specific antimuscaranic and antispasmodics for overactive bladder in pre-clinical and clinical development, including darifenacin by Pfizer Inc.

. With respect to citicoline, Genentech, Inc. markets Activase, a

thrombolytic agent, as a treatment for stroke. We are aware that other companies are conducting clinical trials on a number of other products for stroke which could also compete with citicoline.

- . In addition to PRO 2000, many new substances are being evaluated for the prevention of HIV transmission. Among the most advanced are BufferGel, Savvy, Emmelle, Carraguard and cellulose sulfate gel.
- . Dersalazine initially would compete with various formulations of 5-aminosalicylic acid often used as first line therapy for inflammatory bowel disease and including Asacol, Dipentum, Pentasa and Colazal.

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 us. We may not be able to develop products that are more effective or achieve greater market acceptance than competitive products. In addition, our competitors may develop products that are safer or more effective or less expensive than those we are developing or that would render our products less competitive or obsolete. As a result, our products may not be able to compete successfully. In addition, royalties payable to us under certain conditions may be reduced or eliminated if there is generic competition.

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, we compete with universities and other research institutions in the development of products, technologies and processes.

Our company is controlled by certain stockholders.

Our executive officers, directors and principal stockholders (including individuals or entities related to such stockholders) own or control approximately 24% (excluding any options or warrants) of our outstanding Common Stock. Accordingly, these officers, directors and stockholders may have the ability to exert significant influence over the election of our Board of Directors and to determine corporate actions requiring stockholder approval.

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

Our Board of Directors has the authority, without further approval of our 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 our Common Stock subject to stock awards under our 1997 Equity Incentive Plan accelerates and outstanding options under our stock option plans become immediately exercisable upon certain changes in control of Interneuron, 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 the Company and, accordingly, could adversely affect the price of our Common Stock.

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We have never paid any dividends on our Common Stock.

We have not paid any cash dividends on our Common Stock since inception and do not expect to do so in the foreseeable future. Any dividends will be subject to the preferential cumulative dividend of \$0.1253 per share and \$1.00 per

share payable on our outstanding Series B Preferred Stock and Series C Preferred Stock, respectively, held by American Home Products Corporation and dividends payable on any other preferred stock we may issue.

Our stock price is volatile.

The market prices for our securities and for securities of emerging growth companies have historically been highly volatile. Future announcements concerning us or our competitors may have a significant impact on the market price of our Common Stock. Factors which may affect our market price include:

- . results of clinical studies and regulatory reviews;
- . changes in the levels we spend to develop, acquire or license new compounds;
- . announcements by our corporate collaboration partners concerning our products, about which we generally have very limited control, if any, over the timing or content;
- . market conditions in the pharmaceutical and biotechnology industries;
- . competitive products;
- . financings or corporate collaborations;
- . sales or the possibility of sales of our Common Stock;
- . our results of operations and financial condition including variability in quarterly operating results due to timing and recognition of revenues and expenses, receipt of licensing, milestone and royalty payments, and regulatory progress and delays;
- . proprietary rights;
- . Redux-related litigation developments;
- . public concern as to the safety or commercial value of our products; and
- . general economic conditions.

The high and low sales prices of our Common Stock as reported by Nasdaq National Market were: \$6.25 and \$1.13 for fiscal 1999, \$8.75 and \$1.34 for fiscal 2000, \$10.00 and \$1.16 for fiscal 2001 and \$12.32 and \$4.55 for the quarter ended December 31, 2001.

The uncertainties associated with the Redux-related litigation have adversely affected and may continue to adversely affect the market price of our Common Stock. Furthermore, the stock market has experienced significant price and volume fluctuation unrelated to the operating performance of particular companies. These market fluctuations may also adversely affect the market price of our Common Stock.

Our stock price could be negatively affected if our shares are sold, if we issue additional shares or if third parties exercise registration rights.

As of December 31, 2001, we had 46,426,349 shares of Common Stock outstanding. Substantially all of these shares, other than 3,125,000 which are covered by this prospectus, are unrestricted securities and may be sold to the public by the owners without restriction. However, some of our stockholders own restricted securities, and they may have to rely on Rule 144 of the Securities Act of 1933 which regulates the sale of restricted securities. In general,

under Rule 144 as currently in effect, a person (or persons whose shares are aggregated), including persons who may be deemed to be "affiliates" of our company as that term is defined under the

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Securities Act of 1933, is entitled to sell within any three-month period a number of restricted shares beneficially owned for at least one year that does not exceed the greater of:

(i) one percent of the then outstanding shares of Common Stock, or

(ii) the average weekly trading volume in the Common Stock during the four calendar weeks preceding such sale.

Sales of restricted securities under Rule 144 of the Securities Act of 1933 are also subject to certain requirements as to the manner of sale, notice and the availability of current public information about us. However, a person who is not an affiliate and has beneficially owned such shares for at least two years is entitled to sell such shares without regard to the volume or other requirements.

American Home Products Corporation has the right, under certain circumstances, to require us 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. We have outstanding registration statements on Form S-3 relating to the resale of our shares of Common Stock and on Form S-8 relating to shares issuable under our 1989 Stock Option Plan, 1994 Long-Term Incentive Plan, 1995 Employee Stock Purchase Plan, 1997 Equity Incentive Plan, 1998 Employee Stock Option Plan and 2000 Stock Option Plan.

The recipients of shares of our Common Stock under the 1997 Equity Incentive Plan can sell these shares immediately upon the expiration of certain waiting periods called vesting periods. As of December 31, 2001, of the 1,736,918 shares of Common Stock issued or issuable pursuant to stock awards under the 1997 Equity Incentive Plan, 1,511,918 shares were issued after expiration of vesting periods and 225,000 shares subject to outstanding awards vest through April 2002. The vesting dates are subject to extension if they occur during a "Black Out Period." Black Out Periods generally are periods in which the recipient is unable to sell the shares subject to the award at the applicable vesting date due to legal or contractual restrictions. The vesting dates are also subject to acceleration under certain circumstances, including certain changes in control of the Company, except under certain conditions.

Sales of the shares of Common Stock subject to restricted stock awards, 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 our Common Stock.

Our stockholders could be diluted if we issue our shares subject to options, warrants, stock awards or other arrangements.

As of December 31, 2001, we had reserved the following shares of Common Stock for issuance:

. 10,473,000 shares issuable upon exercise of outstanding options and warrants, 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 and warrant holders if we issue additional securities below certain prices;

- . 225,000 shares issuable, at nominal consideration, upon vesting of stock awards under the Company's 1997 Equity Incentive Plan;
- . 622,222 shares upon conversion of Preferred Stock owned by American Home Products Corporation, subject to anti-dilution provisions; and
- . 987,000 shares reserved for grant and issuance under the Company's stock option plans, stock purchase plan and equity incentive plan.

We may grant additional options, warrants or stock awards. In addition, we may be required to issue additional shares of Common Stock in connection with technology acquisitions. To the extent such shares are issued, the interest of holders of Common Stock will be diluted.

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USE OF PROCEEDS

To the extent any of the Shares are sold, each Selling Stockholder will receive all the net proceeds from the sale of those Shares. We will not receive any of the net proceeds from the sale of the Shares offered by the Selling Stockholders. See "Plan of Distribution."

SELLING STOCKHOLDERS

We are registering for resale the Shares held by the Selling Stockholders identified below to permit the Selling Stockholders to resell the Shares. Pursuant to the Stock Purchase Agreements dated as of December 20, 2001 between us and each of the Selling Stockholders, other than Mr. Sharrock, we issued and sold 3,125,000 shares for an aggregate purchase price of \$25,000,000 (the "Offering"). In addition to the shares sold in the Offering, we are also registering for resale 50,000 shares which are issuable upon exercise of an option we granted to Mr. Sharrock, one of our Directors. The Selling Stockholders may, from time-to-time, offer and resell such shares after the effective date of this prospectus. We agreed that all such shares of Common Stock are to be registered with the Securities and Exchange Commission.

The table below presents information as of January 4, 2002, regarding the Selling Stockholders and the Shares that they may offer and sell from time-to-time under this prospectus. This table is prepared based on information supplied to us by the listed Selling Stockholders. The table assumes that the Selling Stockholders sell all of the Shares offered under this prospectus. However, because the Selling Stockholders may offer from time-to-time all, some, or none of their Shares pursuant to this prospectus, or in another permitted manner, we cannot assure you as to the actual number of the Shares that will be sold by the Selling Stockholders or that will be held by the Selling Stockholders may change from time-to-time, and changed information will be presented in a supplement to this prospectus if and when necessary and required.

We have agreed, among other things, to bear certain expenses in connection with the registration and sale of the Shares being offered by the Selling Stockholders. See "Plan of Distribution."

Shares Owned by Shares Owned by Selling Stockholder Number of Selling Stockholder

	Prior to Offering(2)			Shares After Offering(2) Being	
Name of Selling Stockholder(1)	Number	Percent	2		Percent
Ascend Offshore Fund, LTD	100,000(4)	*	69,520	0	0.0%
Ascend Partners, L.P	• • •	*	14,690	0	0.0%
Ascend Partners Sapient, L.P	100,000(4)	*		0	0.0%
Bridgewood Capital Partners, L.P	153,600	*	42,800	110,800	*
Crestwood Capital International, Ltd	717,800	1.5%	202,000	515,800	1.1%
Crestwood Capital Partners, L.P	1,218,800	2.6%	342,500	876,300	1.9%
Crestwood Capital Partners II, L.P	134,800		37,700	97,100	*
Edelman, Joseph	1,890,900(5)	4.1%	300,000	390 , 900(6)	*
Les Fils Dreyfus & Cie	175,000(7)	*	150,000	25,000	*
Perceptive Life Sciences Master Fund, LTD	1,890,900(5)	4.1%	1,200,000	390 , 900(6)	*
Sharrock, David	229,334(8)	*	50,000	179 , 334(9)	*
Welch Capital Partners II, L.L.C	217,650	*	204,080	13 , 570	*
Welch Entrepreneurial Fund, L.P	404,610	*	296,730	107,880	*
Welch Life Sciences Fund, L.P	442,940	1.0%	249,190	193,750	*
Totals			3,175,000		

* Less than 1%

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- (1) Other than David Sharrock, a Director of the Company, none of the other Selling Stockholders nor any of their affiliates, officers, directors or principal equity holders has held any position or office or has had any material relationship with us within the past three years.
- (2) Other than the percentages for Mr. Sharrock, the percentages are based on 46,426,349 shares of our Common Stock that were outstanding on December 31, 2001. The percentages for Mr. Sharrock are based on 46,650,683 shares of our Common Stock that would be outstanding if Mr. Sharrock exercised the options which he holds that are exercisable within 60 days of January 4, 2002.
- (3) Assumes that all shares to be offered are sold pursuant to this offering and that no other shares of Common Stock are acquired or disposed of by the Selling Stockholder.
- (4) Includes 69,520 shares directly owned by Ascend Offshore Fund, LTD, 14,690 shares directly owned by Ascend Partners, L.P. and 15,790 shares directly owned by Ascend Partners Sapient, L.P.
- (5) Includes 340,000 shares directly owned by Mr. Edelman, 96,300 shares directly owned by First New York Securities, LLC and 1,454,600 shares directly owned by Perceptive Life Sciences Master Fund, LTD.
- (6) Includes 40,000 shares directly owned by Mr. Edelman, 96,300 shares directly owned by First New York Securities, LLC and 254,600 shares directly owned by Perceptive Life Sciences Master Fund, LTD.
- (7) Includes 25,000 shares directly owned by Les Fils Dreyfus & Cie prior to the Offering.
- (8) Includes 5,000 shares owned directly and 224,334 shares issuable upon exercise of options exercisable within 60 days of January 4, 2002.
- (9) Includes 5,000 shares owned directly and 174,334 shares issuable upon exercise of options exercisable within 60 days of January 4, 2002.

PLAN OF DISTRIBUTION

The Selling Stockholders and those who purchase the Shares from the Selling

Stockholders will act independently of us in making decisions with respect to the timing, manner and size of any sale of the Shares. The sales may be made on The Nasdaq National Market, on other exchanges or in the over-the-counter market or otherwise, including by those means described below, at prices and at terms then prevailing or at prices related to the then current market price of our Common Stock, or in privately negotiated transactions. Such persons may or may not effect such transactions by selling the Shares to or through broker-dealers. The Shares may be sold by one or more of, or a combination of, the following:

- . cross trades or block trades in which the broker-dealer so engaged will attempt to sell the Shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- . purchases by a broker-dealer as principal and resale by such broker-dealer for its own account pursuant to this prospectus;
- . "at the market" to or through market makers or into an existing market for the Shares;
- . an exchange distribution in accordance with the rules of such exchange;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers which may include long sales or short sales effected after the effective date of the Registration Statement of which this prospectus is a part;
- . transactions in options, swaps or other derivatives (whether exchange-listed or otherwise);
- . in other ways not involving market makers or established trading markets, including direct sales to purchasers or sales effected through agents;
- . any combination of the foregoing practices; or
- . any other lawful method.

In addition, any of the Shares covered by this prospectus which qualify for sale pursuant to Rule 144 or another applicable exemption under the Securities Act may be sold under Rule 144 or such exemption rather than pursuant to this prospectus.

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To the extent required, this prospectus may be amended or supplemented from time-to-time to describe a specific plan of distribution. In effecting sales, broker-dealers engaged by the stockholders may arrange for other broker-dealers to participate in the resales.

The Selling Stockholders may enter into hedging transactions with broker-dealers in connection with distributions of the Shares or otherwise. In such transactions, broker-dealers may engage in short sales of the Shares in the course of hedging the positions they assume with Selling Stockholders. The Selling Stockholders also may sell the Shares short and deliver the Shares to close out such short positions. The Selling Stockholders may enter into option or other transactions with broker-dealers which require the delivery to the broker-dealer of the Shares. The broker-dealer may then resell or otherwise transfer such Shares pursuant to this prospectus. The Selling Stockholders also may loan the Shares to a broker-dealer or pledge the Shares. The broker-dealer may sell the Shares so loaned, or upon a default the lender may sell the

pledged Shares pursuant to this prospectus.

Broker-dealers or agents may receive compensation in the form of commissions, discounts or concessions from Selling Stockholders. Broker-dealers or agents may also receive compensation from the purchasers of the Shares for whom they act as agents or to whom they sell as principals, or both. Compensation as to a particular broker-dealer might be in excess of customary commissions and may be in amounts to be negotiated in connection with the sale. Broker-dealers or agents and any other participating broker-dealers or the Selling Stockholders may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act in connection with sales of the Shares. Accordingly, any such commission, discount or concession received by them and any profit on the resale of the Shares purchased by them may be deemed to be underwriting discounts or commissions under the Securities Act. Because Selling Stockholders may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act, the Selling Stockholders will be subject to the prospectus delivery requirements of the Securities Act. We have not been advised that any Selling Stockholders have entered into any agreements, understandings or arrangements with any underwriters or broker- dealers regarding the sale of their Shares.

The Shares may be sold through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states the Shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the Shares may not simultaneously engage in market-making activities with respect to the Shares for a period of two business days prior to the commencement of such distribution. In addition, each Selling Stockholder will be subject to applicable provisions of the Exchange Act and the associated rules and regulations under the Exchange Act, including Regulation M, which provisions may limit the timing of purchases and sales of the Shares by the Selling Stockholders. We will make copies of this prospectus available to the Selling Stockholders, and we have informed them of the need for delivery of copies of this prospectus to purchasers at or prior to the time of any sale of the Shares.

We will file a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act upon being notified by a Selling Stockholder that any material arrangement has been entered into with a broker- dealer for the sale of the Shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer. Such supplement will disclose:

- . the name of each such Selling Stockholder and of the participating broker-dealer(s);
- . the number and type of shares involved;
- . the price at which such shares were sold;
- . the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable;

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. that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus; and

. other facts material to the transaction.

In addition, upon being notified by a Selling Stockholder that a donee or pledgee of such Selling Stockholder intends to sell the Shares, we will consider filing an amendment to this prospectus for purposes of registering the Shares, but only if the donee or pledgee pays for all fees and costs related thereto.

We will bear all costs, expenses, and fees in connection with the registration of the Shares. The Selling Stockholders will bear all selling commissions and underwriting discounts, if any, attributable, to the sales of the Shares. We have agreed to indemnify the Selling Stockholders against certain liabilities, including liabilities under the Securities Act. Pursuant to the Stock Purchase Agreements, the Selling Stockholders have agreed to indemnify us against certain civil liabilities, including certain liabilities under the Securities Act. Also, the Selling Stockholders may agree to indemnify any broker-dealer or agent that participates in transactions involving sales of the Securities Act.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission (the "Commission"), Washington, D.C. a Registration Statement on Form S-3, as amended, under the Securities Act covering the Shares offered by this prospectus. This prospectus does not contain all of the information set forth in the Registration Statement and the exhibits thereto. Statements made in this prospectus as to the contents of any contract, agreement or other document referred to are not necessarily complete and in each instance such statement is qualified by reference to each such contract, agreement or document.

We are subject to the informational requirements of the Exchange Act, and in accordance therewith file reports and other information with the Commission. These annual, quarterly and special reports, proxy statements and other information may be inspected, and copies of these materials may be obtained upon payment of the prescribed fees, at the Commission's Public Reference Room, Room 1024, 450 Fifth Street, Suite 1300, N.W., Washington, D.C. 20549. In addition, we are required to file electronic versions of these materials with the Commission through the Commission's Electronic Data Gathering, Analysis and Retrieval (EDGAR) system. Please call the Commission at 1-800-SEC-0330 for more information about the operation of the public reference room. The Commission also maintains a Web site at http://www.sec.gov that contains reports, proxy statements and other information regarding issuers that file electronically with the Commission. Our Common Stock is quoted on The Nasdaq National Market. Reports, proxy statements and other information concerning us may also be reviewed at our Internet Site: http://www.interneuron.com.

INFORMATION INCORPORATED BY REFERENCE

THIS PROSPECTUS IS PART OF A REGISTRATION STATEMENT ON FORM S-3 WE FILED WITH THE SECURITIES AND EXCHANGE COMMISSION. YOU SHOULD RELY ONLY ON THE INFORMATION CONTAINED IN THIS PROSPECTUS OR INCORPORATED BY REFERENCE. WE HAVE NOT AUTHORIZED ANYONE ELSE TO PROVIDE YOU WITH DIFFERENT INFORMATION. WE ARE NOT MAKING AN OFFER OF THESE SECURITIES IN ANY STATE WHERE THE OFFER IS NOT PERMITTED. YOU SHOULD NOT ASSUME THAT THE INFORMATION IN THIS PROSPECTUS IS ACCURATE AS OF ANY DATE OTHER THAN THE DATE ON THE FRONT PAGE OF THIS PROSPECTUS, REGARDLESS OF THE TIME OF DELIVERY OF THIS PROSPECTUS OR ANY SALE OF COMMON STOCK.

This prospectus does not contain all of the information set forth in the Registration Statement. The Commission allows us to "incorporate by reference"

information that we file with them, which means that we

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can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the Commission will automatically update and supersede this information. Further, all filings we make under the Exchange Act after the date of the initial Registration Statement and prior to effectiveness of the Registration Statement shall be deemed to be incorporated by reference into this prospectus. We incorporate by reference the documents listed below and any future filings we will make with the Commission under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act:

(i) Our Annual Report on Form 10-K for the fiscal year ended September30, 2001, including all material incorporated by reference therein;

(ii) Our Current Report on Form 8-K having a report date of December 18, 2001;

(iii) Our Current Report on Form 8-K having a report date of December 21, 2001;

(iv) All other reports filed by us pursuant to Section 13(a) or 15(d) of the Exchange Act, since September 30, 2001; and

(v) The description of our Common Stock, 001 par value per share, which is set forth in our Registration Statement on Form 8-A declared effective on March 8, 1990, as amended.

We will provide without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request of such person, a copy of any and all of the documents that have been incorporated by reference in this prospectus (not including exhibits to such documents, unless such exhibits are specifically incorporated by reference in this prospectus or into such documents). Such request may be directed to: Interneuron Pharmaceuticals, Inc., One Ledgemont Center, 99 Hayden Avenue, Lexington, Massachusetts 02421-7966, Attention: Chief Financial Officer, telephone (781) 861-8444.

LEGAL MATTERS

The validity of the securities offered hereby were passed upon for us by Burns & Levinson LLP, Boston, Massachusetts.

EXPERTS

The financial statements incorporated in this prospectus by reference to the Annual Report on Form 10-K of Interneuron Pharmaceuticals, Inc. for the year ended September 30, 2001, have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, independent accountants, given on the authority of said firm as experts in auditing and accounting.

INDEMNIFICATION OF OFFICERS AND DIRECTORS

Article Seventh of the our Restated Certificate of Incorporation, as amended, states that we shall indemnify any person to the full extent permitted by the Business Corporation Law of the State of Delaware, as the same now exists or may hereafter be amended.

In addition to our Restated Certificate of Incorporation, Article V of our By-Laws states that we shall, to the fullest extent permitted by the laws of the state of incorporation, indemnify any and all persons whom we shall have the power to indemnify against any and all of the costs, expenses, liabilities or other matters incurred by such person by reason of having been officers or directors of the Company, any subsidiary of the Company or of any other corporation for which such person acted as officer or director at the request of the Company.

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Subsection (a) of Section 145 of the Delaware General Corporation Law empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that the person's conduct was unlawful.

Subsection (b) of Section 145 empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Section 145 further provides that to the extent a director, officer or former director or officer, of a corporation has been successful in the defense of any action, suit or proceeding referred to in subsection (a) and (b) or in the defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by him or her in connection therewith. Section 145 also provides that expenses (including attorneys' fees) incurred by an officer or

director in defending any civil, criminal, administrative or investigative action, suit or proceeding may be paid by the corporation, upon such terms and conditions, if any, as the corporation deems appropriate, in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that such person is not entitled to be indemnified by the corporation as authorized in Section 145.

Section 145 additionally provides that the indemnification provided by Section 145 shall not be deemed exclusive of any other rights to which the indemnified party may be entitled; and that the scope of indemnification extends to directors, officers, employees, or agents of a constituent corporation absorbed in a consolidation or merger and persons serving in that capacity at the request of the constituent corporation for another.

Section 145 also empowers a corporation to purchase and maintain insurance on behalf of any person who is or was a director or officer of the corporation against any liability asserted against such person or incurred by such person in any such capacity or arising out of such persons status as such whether or not the corporation would have the power to indemnify such person against such liabilities under Section 145.

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We also have indemnification agreements with our officers and directors and have director and officer liability insurance.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or persons controlling the Company as discussed in the previous section of this prospectus entitled "Indemnification of Officers and Directors", the Company has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

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