NEUROCRINE BIOSCIENCES INC Form 424B5 November 28, 2001

This filing is made pursuant to Rule 424 (b) (5) under the Securities Act of 1933 in connection with Registration No. 333-73216

The information in this preliminary prospectus supplement and the accompanying prospectus is not complete and may be changed. A registration statement relating to these securities has been filed with the Securities and Exchange Commission and has been declared effective. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities and are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Preliminary Prospectus Supplement to Prospectus Dated November 20, 2001 Subject to Completion, Dated November 28, 2001

3,250,000 Shares

Common Stock

This is a public offering of common stock of Neurocrine Biosciences, Inc. We are offering 3,250,000 shares of our common stock. Our common stock is traded on the Nasdaq National Market under the symbol NBIX. On November 23, 2001, the last reported sale price of our common stock was \$47.90 per share.

Investing in the common stock involves risk. See Risk Factors beginning on page S-7.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the prospectus to which it relates. Any representation to the contrary is a criminal offense.

	Per Share	l otal
Public offering price	\$	\$
Underwriting discounts and commissions	\$	\$
Proceeds, before expenses, to Neurocrine	\$	\$

We have granted the underwriters the right to purchase up to 487,500 additional shares of common stock to cover over-allotments.

Joint Bookrunning Managers

Deutsche Banc Alex. Brown Credit Suisse First Boston

CIBC World Markets Lehman Brothers UBS Warburg

The date of this prospectus supplement is , 2001.

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement is a supplement to the accompanying prospectus that is also a part of this document. This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the Securities and Exchange Commission using a shelf registration process. Under the shelf registration process, we may sell any combination of the securities described in the accompanying prospectus up to a total dollar amount of \$200,000,000, of which this offering is a part. In this prospectus supplement, we provide you with specific information about the terms of this offering and certain other information. Both this prospectus supplement and the accompanying prospectus include important information about us, our common stock and other information you should know before investing in our common stock. This prospectus supplement and the accompanying prospectus also incorporate important business and financial information about Neurocrine Biosciences, Inc. and its subsidiaries that is not included in or delivered with these documents. You should read both this prospectus supplement and the accompanying prospectus as well as the additional information described under the heading. Where You Can Find More Information beginning on page S-63 of this prospectus supplement before investing in our common stock. This prospectus supplement adds, updates and changes information contained in the accompanying prospectus and the information incorporated by reference. To the extent that any statement that we make in this prospectus supplement is inconsistent with the statements made in the accompanying prospectus are deemed modified or superseded by the statements made in this prospectus supplement.

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SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus supplement. This summary may not contain all of the information that you should consider before investing in our common stock. You should carefully read the entire prospectus supplement, the accompanying prospectus and the documents incorporated by reference therein.

Our Business

Neurocrine Biosciences, Inc. develops and intends to commercialize drugs for the treatment of neurologic and endocrine system-related diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world, including insomnia, anxiety, depression, cancer, diabetes and multiple sclerosis. We currently have 15 programs in various stages of research and development, including seven programs in clinical development and one program in advanced preclinical development. Our lead clinical development program is a drug for the treatment of insomnia currently being evaluated in Phase III clinical trials.

While we independently develop the majority of our product candidates, we have entered into collaborations for five of our 15 programs. We have entered into collaboration agreements with GlaxoSmithKline, Wyeth-Ayerst, a division of American Home Products, Taisho Pharmaceutical, Janssen Pharmaceutica, a subsidiary of Johnson & Johnson, and Eli Lilly.

Our Product Candidates

Our clinical development programs address large potential markets in a broad range of disease. These are summarized as follows:

Insomnia. Our most advanced product candidate, NBI-34060, is currently being evaluated in Phase III clinical trials for insomnia. Insomnia is a prevalent neurological disorder, with approximately one-half of the U.S. adult population reporting trouble sleeping a few nights per week or more, according to the National Sleep Foundation. According to Med Ad News, worldwide sedative sales in 2000 totaled approximately \$2.0 billion. However, many sedatives have side effects, including next day residual sedation effects. In addition, existing drugs are restricted to short term use and are not approved for dosing in the middle of the night or to maintain sleep throughout the night. As a result, we believe there is a significant unmet medical need for an improved sedative.

We have completed 19 Phase I and Phase II clinical trials of NBI-34060 for efficacy and safety involving more than 1,100 subjects. Results from these trials demonstrate that NBI-34060 significantly decreases time to sleep onset in both transient and chronic insomnia subjects without evidence of increased unwanted side effects or next day residual sedation as compared to placebo. In several of these studies, we observed that NBI-34060 increased sleep duration and reduced the number of nighttime awakenings. The compound was also shown in Phase II trials to be safe when used in the middle of the night.

Based upon the positive results from these Phase II trials, we have planned a comprehensive Phase III clinical program involving approximately 2,200 subjects in seven large

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clinical trials to confirm the safety and efficacy of NBI-34060 and to differentiate the compound from other sleep medicines. In November 2001, we initiated our first Phase III clinical trial of NBI-34060 in approximately 500 patients to evaluate two doses of an immediate release formulation of NBI-34060 for long-term treatment of chronic insomnia.

Depression and Anxiety. Our product candidate, NBI-34041, is currently being evaluated in Phase I clinical trials for depression and anxiety. Depression and anxiety are two of the most common psychiatric disorders. Researchers believe that a chemical known as a corticotropin-releasing factor, or CRF, is overproduced in the brains of individuals with clinical depression and anxiety. NBI-34041 is one of a new class of compounds that functions by attaching to the receptors for CRF, thereby antagonizing, or blocking, its activity.

We have intellectual property rights to two receptors for CRF and have developed numerous classes of novel small molecule drugs to block these receptors. In August 2001, we began a collaboration with GlaxoSmithKline, or GSK, to develop and commercialize a new class of CRF antagonists, including NBI-34041. We have completed two Phase I safety trials of NBI-34041 and together with GSK expect to initiate further safety and efficacy trials in 2002. We also have a backup CRF antagonist in preclinical development, which we expect will advance into Phase I trials in 2002.

Cancer. Our product candidate, NBI-3001, is in Phase II clinical trials for malignant glioma, an aggressive form of brain cancer, and is currently being evaluated in a Phase I safety trial for kidney, lung and breast cancer. Interleukin-4, or IL-4, is a natural substance that modulates cell growth. Cell surface proteins that bind to IL-4, known as IL-4 receptors, are highly concentrated on the cells of malignant brain tumors as well as many other cancers, including some types of kidney, lung and breast cancer. By attaching a toxic agent to the IL-4 protein, we may preferentially target the IL-4 receptors and thus selectively kill cancer cells.

In malignant glioma, we have completed two Phase II clinical trials. In the first trial, completed in February 2000, NBI-3001 demonstrated an acceptable safety and tolerability profile. In addition, of the 27 patients who completed therapy, 63% showed complete or partial reduction in tumor size at least once during follow-up. In the second Phase II clinical trial, we tested the compound in 18 patients to confirm the optimum dosing schedule for Phase III trials. We expect to meet with the FDA in early 2002 to discuss the requirements for our Phase III trials. In addition, if the Phase I safety trial in the U.S. for kidney, lung and breast cancer proves successful, we expect to move into Phase II efficacy trials in the second half of 2002. The FDA has awarded fast track and orphan drug status for this drug candidate for treatment of a certain type of glioma. We have maintained worldwide commercial rights to NBI-3001 for oncology uses and an exclusive option for all other therapeutic uses.

Multiple Sclerosis. We have completed two Phase II safety and preliminary efficacy trials for our product candidate, NBI-5788, in patients with a recurring form of multiple sclerosis. In autoimmune diseases such as multiple sclerosis, T cells, which ordinarily target infectious agents, may mistake normally occurring proteins in the central nervous system as foreign. In multiple sclerosis, this protein is called myelin, and destruction of the myelin which surrounds the nerve fibers in the brain and spinal cord leads to neurologic dysfunction and degeneration of the central nervous system. By altering the structure of this protein using our altered peptide ligand technology, we believe that NBI-5788 may prevent T cells from destroying healthy tissue.

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We have maintained worldwide commercial rights to NBI-5788. We are currently in the process of preparing a clinical development plan for confirmatory Phase II trials for this product candidate to determine optimal dose and frequency of administration.

Diabetes. Our drug candidate, NBI-6024, is currently being tested in a Phase II clinical trial in patients with Type I diabetes. In Type I diabetes, as in multiple sclerosis, the immune system erroneously targets healthy tissue in this case the pancreatic cells responsible for the production of insulin. By altering the structure of certain proteins in these cells, we believe that NBI-6024 may prevent the destruction of insulin-secreting cells, allowing patients to delay or avoid chronic insulin therapy.

We have completed several safety trials in approximately 100 diabetic patients, which have demonstrated that our compound was safe and well tolerated. We recently initiated a 386-patient Phase II efficacy trial and expect to initiate a second 300-patient Phase II trial in early 2002. We are developing this drug candidate in worldwide collaboration with Taisho Pharmaceutical.

Hormone dependent disease. Gonadotropin-releasing hormone is a hormone that regulates sex steroid production and normal reproductive function. Researchers have linked elevated levels of this hormone to diseases such as prostate cancer and endometriosis, a common uterine disease. We have developed antagonists of the receptors for this hormone, and initiated Phase I safety trials in November of this year. Current treatments for these diseases are large molecule drugs administered by injection. Our drug candidates, if successfully commercialized, would be administered orally.

Research. We have seven additional research programs in areas such as neurodegenerative disease, obesity, and gastrointestinal, sleep and eating disorders. We believe that these research programs will supply clinical development candidates in the future.

Our Business Strategy

Our strategy is to build a large and diversified product portfolio, which we believe maximizes our commercial opportunity and reduces overall clinical and technical risk. We focus on drug candidates that we believe address large unmet market opportunities. We pursue this strategy through internal drug development efforts, through collaborations with global pharmaceutical companies and by acquiring rights to complementary drugs. In conducting our drug development efforts, we collaborate with platform technology companies to supplement our research capabilities, and we generally outsource capital intensive, non-strategic activities.

Other Information

We were incorporated in California in 1992 and reincorporated in Delaware in 1996. Our common stock began trading publicly in May 1996. Our headquarters are located at 10555 Science Center Drive, San Diego, California 92121. Our telephone number is (858) 658-7600. Our website is www.neurocrine.com, but the information on this website does not constitute a part of this prospectus supplement.

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The Offering

Common stock offered by Neurocrine 3,250,000 shares

Common stock to be outstanding after this offering 29,476,218 shares

Use of proceeds For research and product development, potential technology

acquisitions, working capital and general corporate purposes.

Nasdag National Market symbol NBIX

The number of shares of our common stock outstanding after the offering is based on the number of shares outstanding as of November 16, 2001. This number does not include:

3,952,380 shares of common stock reserved for the exercise of options outstanding at a weighted average exercise price of \$18.34 per share;

430,504 shares of common stock reserved for the exercise of warrants outstanding at a weighted average exercise price of \$14.72 per share;

174,524 shares of common stock reserved for issuance under our employee stock purchase plan; and

874,735 shares of common stock reserved for issuance under our other stock incentive plans.

Unless otherwise indicated, the information in this prospectus supplement assumes no exercise of the underwriters over-allotment option.

Neurocrine Biosciences is a registered trademark of Neurocrine Biosciences, Inc. All other brand names, trademarks and service marks appearing in this prospectus supplement and the accompanying prospectus are the property of their respective holders.

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(in thousands, except per share data)

The following table is a summary of our consolidated financial data for the periods presented. You should read this data along with Management's Discussion and Analysis of Financial Condition and Results of Operations included in this prospectus supplement, and our financial statements and related notes in our most recent Annual Report on Form 10 K and Quarterly Report on Form 10 Q, each filed with the Securities and Exchange Commission and incorporated by reference in this prospectus supplement and the accompanying prospectus. The summary financial data for the nine months ended September 30, 2000 and 2001 have been derived from unaudited financial statements. Historical results are not necessarily indicative of results to be expected for any future period.

	Nine Months
	Ended
Years Ended December 31,	September 30,