



NEWS RELEASE - *for immediate release*

Alexza Updates Status of Development Pipeline and Summarizes 2007 Corporate Goals

Initial Results Expected to be Reported in Q1 2007 for AZ-001 Phase IIb and AZ-004 Phase IIa Clinical Studies

Palo Alto, California - February 8, 2007 - Alexza Pharmaceuticals, Inc. (Nasdaq: ALXA) announced today an update of its product candidate development pipeline and a summary of its 2007 goals.

“Last year was very important for Alexza,” said Thomas B. King, President and CEO. “We completed our IPO, initiated four clinical studies with four different product candidates and completed our first development agreement for Staccato[®]-based products. During 2007, investors will have the opportunity to see results from the clinical trials we initiated last year, as we complete the enrollment in the studies and release initial results. In addition, we have set aggressive corporate goals for the company, to continue the progress and momentum we have established during the past several years.”

Recent Alexza Development Pipeline Highlights and Updates

- **AZ-001 (*Staccato prochlorperazine*) for the treatment of migraine.** In December 2006, Alexza announced the completion of enrollment in its 400 patient Phase IIb clinical trial with AZ-001. Initial results are expected to be reported in late March 2007. Using the International Headache Society 4-point rating scale, the primary efficacy endpoint for the trial is headache pain relief at 2 hours post-dose. Secondary efficacy endpoints for the trial include pain relief and other symptom assessments at various time points. Safety evaluations were made throughout the clinical trial. After the trial results are released, Alexza expects to provide information on specific 2007 development activities for AZ-001, based upon the efficacy and safety findings from the clinical trial.
- **AZ-004 (*Staccato loxapine*) for the treatment of acute agitation in schizophrenia.** In January 2007, Alexza announced the completion of enrollment in its 120 patient, in-clinic Phase IIa clinical trial with AZ-004. The clinical trial enrolled faster than originally projected and initial results are now expected to be reported in late March 2007. The primary aim of the clinical trial was to assess the safety and efficacy of a single dose of AZ-004 in acutely treating agitation in schizophrenic patients. Assessments of a patient’s agitation state were conducted at serial time points using both standard agitation scales and objective measures of patient’s movement over a 4-hour period, with follow-up assessments for the next 20 hours. The change in the PANSS Excited Component (PEC) scale is the primary efficacy endpoint for the clinical study. Safety evaluations were made throughout the clinical trial period.

- **AZ-003 (*Staccato* fentanyl) for the treatment of acute pain episodes.** In December 2006, the Company completed enrollment and announced initial results from its Phase I clinical trial with AZ-003. The clinical trial was conducted in opioid naive healthy volunteers in two stages. In Stage 1, the arterial pharmacokinetics (PK) of 25 µg of AZ-003 was compared to a 25 µg dose of fentanyl administered intravenously (IV). The AZ-003 PK was equivalent to the IV fentanyl PK, with similar peak plasma concentration (C_{max}), time to maximum plasma concentration (T_{max}), and area under the curve concentration (AUC). These data suggest complete bioavailability of the inhaled dose. Mean peak arterial plasma concentrations were observed within 30 seconds for both administration routes. In Stage 2 of the clinical trial, ascending doses of AZ-003, controlled by the *Staccato* system, exhibited dose-proportionality of fentanyl throughout the dosing range from 50 µg to 300 µg, following an AUC analysis. There were no serious adverse events attributable to AZ-003 and the results from the clinical study showed that AZ-003 was generally safe and well tolerated at all doses. During 2007, final study reports will be completed and Alexza plans to present data from this study in both scientific and medical forums. This is the first product candidate under development utilizing Alexza's *Staccato* Electric Multiple Dose (EMD) system, and Alexza plans no additional clinical development of AZ-003 during 2007, unless it is able to secure a corporate partner to support continued clinical and device development.

- **AZ-002 (*Staccato* alprazolam) for the treatment of acute panic.** During 2006, Alexza initiated a Phase IIa proof-of-concept clinical trial with AZ-002 in patients with panic disorder. The primary aim of the clinical trial is to assess the safety and efficacy of a single dose of AZ-002 in treating a pharmacologically-induced panic attack. Changes in the intensity and the duration of the induced panic attack, using psychological and physiological measurements, are being evaluated at multiple time points during the study. Some of the first patients dosed in the study exhibited a higher level of sedation than had been observed at the same dose in healthy volunteers in the AZ-002 Phase I study. In consultation with the clinical investigator, Alexza modified the protocol to reduce the dose of AZ-001 and to include an open label lead-in stage of the study in which patient sedation will be assessed. Once an acceptable dose of AZ-002 is determined from this lead-in stage, the randomized, double-blind proof-of-concept stage of the study will begin, as originally designed. To facilitate patient enrollment in the clinical trial, Alexza has also recruited two additional clinical sites to conduct the study. In the manufacture of the new dosage strengths required for the amended protocol, a higher variability of the alprazolam emitted dose was observed. Further testing showed that alprazolam aerosols are electrically charged leading to variable deposition on the internal airway housing of the device. This aerosol characteristic is unique to alprazolam and is not observed in other Alexza development product candidates. Consequently, the manufacturing process for AZ-002 was modified to incorporate a conductive airway housing to reduce the effects of the electrically charged aerosol. Alexza has manufactured AZ-002 using the new airway housing, which the Company believes resolves the aerosol variability. Alexza is currently projecting that the AZ-002 Phase IIa study will be completed by the end of 2007.



- **Symphony Allegro.** In December, Alexza announced a \$50 million development agreement for AZ-002 and AZ-004. Under the terms of the development agreement, Alexza and Symphony Capital, a private equity firm, have established Symphony Allegro, Inc., which will provide funding to Alexza to support clinical and other related development activities of the two product candidates. The primary goal of the development agreement is to complete successful end-of-Phase II meetings with the U.S. Food and Drug Administration for both product candidates. Key planned development activities during 2007 for AZ-002 include the completion of the Phase IIa proof-of-concept study, the initiation of an abuse liability study and supporting ongoing non-clinical studies. Key planned development activities during 2007 for AZ-004 include the data analysis and release of initial results of the Phase IIa proof-of-concept study in agitated schizophrenic patients, the initiation of a multiple-dose pharmacokinetic study and supporting ongoing non-clinical studies. Symphony Allegro will also support the evaluation of additional indications for both product candidates resulting from the *Staccato*-based pharmacology of alprazolam and loxapine.

In addition to the update on its clinical development candidates, Alexza is reporting the following updates to its business:

- Consistent with previous financial guidance and based on current spending projections, Alexza believes it has cash resources to fund operations through at least the end of the first quarter of 2008. The Company plans on updating financial guidance for 2007 when it releases results for each quarter or upon the announcement of material corporate events.
- Alexza plans to file a new IND during the last quarter of 2007 for a currently unannounced product candidate.
- Alexza intends to seek additional development partnerships during 2007. The range of partnering opportunities for these development partnerships include a commercialization agreement for AZ-001, a development partnership for the *Staccato* EMD platform (including AZ-003) or a development partnership for a non-Alexza selected, new chemical entity which would be incorporated into the *Staccato* system. Alexza may not be able to complete a development partnership on acceptable terms and will only execute the partnership if the Company believes it is in the Company's best interest.

About Alexza Pharmaceuticals

Alexza is an emerging pharmaceutical company focused on the development and commercialization of novel, proprietary products for the treatment of acute and intermittent conditions. The Company's technology, the *Staccato* system, vaporizes unformulated drug to form a condensation aerosol that allows rapid systemic drug delivery through deep lung inhalation. The drug is quickly absorbed through the lungs into the bloodstream, providing speed of therapeutic onset that is comparable to intravenous



administration, but with greater ease, patient comfort and convenience. The Company has four product candidates in clinical development; AZ-001 (*Staccato* prochlorperazine) for the acute treatment of migraine headaches, AZ-002 (*Staccato* alprazolam) for the acute treatment of panic attacks associated with panic disorder, AZ-004 (*Staccato* loxapine) for the treatment of acute agitation in patients with schizophrenia and AZ-003 (*Staccato* fentanyl) for the treatment of patients with acute pain.

Safe Harbor Statement

This press release includes forward-looking statements regarding the development of the Company's product candidates, projected clinical trial enrollment and data reporting timelines, entering into development partnership agreements, adequacy of the Company's cash resources to fund the Company's operations, changes in clinical trial and device designs to resolve observed issues in the Company's clinical trials and safety of the Company's products and technologies. Any statement describing the Company's plans, expectations or beliefs is a forward-looking statement, as defined in the Private Securities Litigation Reform Act of 1995, and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of developing and commercializing drugs. The Company's forward-looking statements also involve assumptions that, if they prove incorrect, would cause its results to differ materially from those expressed or implied by such forward-looking statements. These and other risks concerning the Company's business are described in additional detail in the Company's Form S-1 dated March 8, 2006, and the Company's Quarterly and Current Reports filed with the Securities and Exchange Commission, including the risks under the headings "Failure or delay in commencing or completing clinical trials for our product candidates could harm our business", "If our product candidates do not meet safety and efficacy endpoints in clinical trials, they will not receive regulatory approval, and we will be unable to market them.", "If we enter into strategic partnerships, we may be required to relinquish important rights to and control over the development of our product candidates or otherwise be subject to terms unfavorable to us." and "We will need substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.". Forward-looking statements contained in this announcement are made as of this date, and we undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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