CLAIMS

What is claimed:

1. A compound that is 1-(2,6-Bis-methylamino-8-propylamino-pyrimido[5,4-d]pyrimidin-4-yl amino)-2-methyl-propan-2-ol (**31**) or at least one crystalline salt selected from the group consisting of:

(i) Crystalline hydrochloride salt (**31a**), with a XRPD spectrum as per FIG. 3A; XRPD peaks as per FIG. 3B; and/or DSC spectrum as per FIG. 3C;

(ii) Crystalline bis-hydrochloride salt (**31b**), with a XRPD spectrum as per FIG. 4A; XRPD peaks as per FIG. 4B; and/or DSC spectrum as per FIG. 4C;

(iii) Crystalline hydrogen malonate salt (**31c**), with a XRPD spectrum as per FIG. 5A; XRPD peaks as per FIG. 5B; and/or DSC spectrum as per FIG. 5C;

(iv) Crystalline hydrogen maleinate salt Form Male-A (**31d-1**), with a XRPD spectrum as per FIG. 6A; XRPD peaks as per FIG. 6B; and/or DSC spectrum as per FIG. 6C;

(v) Crystalline hydrogen maleinate salt Form Male-B (**31d-2**), with a XRPD spectrum as per FIG. 7A; XRPD peaks as per FIG. 7B; and/or DSC spectrum as per FIG. 7C;

(vi) Crystalline hydrogen fumarate salt (**31e**), with a XRPD spectrum as per FIG. 8A; XRPD peaks as per FIG. 8B; and/or DSC spectrum as per FIG. 8C;

(vii) Crystalline hydrogen L(+)tartrate salt (**31f**), with a XRPD spectrum as per FIG. 9A; XRPD peaks as per FIG. 9B; DSC spectrum as per FIG. 9C;

(viii) Crystalline D,L-mandelate salt (**31g**), with a XRPD spectrum as per FIG. 10A; XRPD peaks as per FIG. 10B; and/or DSC spectrum as per FIG. 10C;

(ix) Crystalline tosylate salt form Tos-A (**31h-1**), with a XRPD spectrum as per FIG. 11A; XRPD peaks as per FIG. 11B; and/or DSC spectrum as per FIG. 11C;

(x) Crystalline tosylate salt form Tos-B (**31h-2**), with a XRPD spectrum as per FIG. 12A; XRPD peaks as per FIG. 12B; and/or DSC spectrum as per FIG. 12C;

(xi) Crystalline mesylate salt (**31i**), with a XRPD spectrum as per FIG. 13A; XRPD peaks as per FIG. 13B; and/or DSC spectrum as per FIG. 13C;

(xii) Crystalline saccharinate salt (**31j**), with a XRPD spectrum as per FIG. 14A; XRPD peaks as per FIG. 14B; and/or DSC spectrum as per FIG. 14C;

and any mixtures thereof.

2. A pharmaceutical composition comprising at least one compound of

claim 1 and at least one pharmaceutically acceptable carrier or excipient.

3. The composition of claim 2, further comprising at least one additional agent selected from the group consisting of doxapram, enantiomers of doxapram, acetazolamide, almitrine, theophylline, caffeine, methylprogesterone and related compounds, sedatives that increase arousal threshold in sleep disordered breathing patients, benzodiazepine receptor agonists, orexin antagonists, tricyclic antidepressants, serotonergic modulators, adenosine and adenosine receptor and nucleoside transporter modulators, cannabinoids, orexins, melatonin agonists, ampakines, sodium oxybate, modafinil, and armodafinil.

4. The composition of claim 3, wherein the compound and the additional agent are physically mixed or physically separated in the composition.

5. The composition of claim 2, further comprising at least one additional agent that causes changes in breathing control.

6. The composition in claim 5, wherein the additional agent is at least one selected from the group consisting of opioid narcotics, benzodiazepines, sedatives, sleeping aids, hypnotics, propofol, and any combinations thereof.

7. The composition of claim 2, wherein the compound is coated onto a base particle so as to form a core.

8. The composition of claim 7, wherein the base particle is not enterically coated and the composition is contained in a pharmaceutically acceptable capsule that is enterically coated.

9. The composition of claim 7, wherein the core is coated with an enteric coating, thereby forming an enterically coated bead.

10. The composition of claim 9, wherein the enterically coated bead is contained in a pharmaceutically acceptable capsule.

11. The composition of claim 10, wherein the capsule contains beads coated with a plurality of enteric coatings, so that the capsule provides delivery of the compound to different regions of the intestine of the subject.

12. The composition of claim 10, wherein the contents of the capsule are dissolved or suspended in a pharmaceutically acceptable liquid as to provide a liquid-filled capsule.

13. The composition of claim 12, wherein the capsule is enterically coated but the liquid formulation contained within does not comprise an enteric coating.

14. A use of at least one compound of claim 1 or a salt, solvate, enantiomer, diastereoisomer or tautomer thereof, in the manufacture of a medicament for preventing or treating a breathing control disorder or disease in a subject in need thereof.

15. The use of claim 14, wherein the breathing control disorder or disease is at least one selected from the group consisting of respiratory depression, sleep apnea, apnea of prematurity, obesity-hypoventilation syndrome, primary alveolar hypoventilation syndrome, dyspnea, altitude sickness, hypoxia, hypercapnia, chronic obstructive pulmonary disease (COPD), sudden infant death syndrome (SIDS), congenital central hypoventilation syndrome, Alzheimer’s disease, Parkinson’s disease, stroke, Duchenne muscular dystrophy, and brain and spinal cord traumatic injury.

16. The use of claim 15, wherein the respiratory depression is caused by an anesthetic, a sedative, a sleeping aid, an anxiolytic agent, a hypnotic agent, alcohol or a narcotic.

17. The use of claim 14, wherein the subject is further administered at least one agent useful for treating the breathing disorder or disease.

18. The use of claim 17, wherein the agent is at least one selected from the group consisting of doxapram, acetazolamide, almitrine, theophylline, caffeine, methylprogesterone and related compounds, sedatives that increase arousal threshold in sleep disordered breathing patients, benzodiazepine receptor agonists, orexin antagonists, tricyclic

antidepressants, serotonergic modulators, adenosine and adenosine receptor and nucleoside transporter modulators, cannabinoids, orexins, melatonin agonists, ampakines, sodium oxybate, modafinil, and armodafinil.

19. The use of claim 17, wherein the compound and the agent are separately administered to the subject.

20. The use of claim 17, wherein the compound and the agent are co-administered to the subject, further wherein the compound and the agent are physically mixed or physically separated when administered to the subject.

21. The use of claim 14, wherein the subject is further administered at least one additional therapeutic agent that changes normal breathing control in the subject.

22. The use of claim 21, wherein that at least one additional agent is selected from the group consisting of opioid narcotics, benzodiazepines, sedatives, sleeping aids, hypnotics, propofol, and any combinations thereof.

23. The use of claim 14, wherein the compound is administered in conjunction with the use of a mechanical ventilation device or positive airway pressure device on the subject.

24. The use of claim 14, wherein the subject is a mammal or bird.

25. The use of claim 24, wherein the mammal is a human.

26. The use of claim 14, wherein the compound is administered to the subject by at least one route selected from the group consisting of nasal, inhalational, topical, oral, buccal, rectal, pleural, peritoneal, vaginal, intramuscular, subcutaneous, transdermal, epidural, intrathecal and intravenous routes.

27. The use of claim 14, wherein the salt comprises an acid addition salt, and the acid is at least one selected from the group consisting of sulfuric, hydrochloric,

hydrobromic, hydroiodic, nitric, carbonic, phosphoric, formic, acetic, propionic, succinic, glycolic, gluconic, lactic, malic, tartaric, citric, ascorbic, glucuronic, maleic, fumaric, pyruvic, aspartic, glutamic, benzoic, anthranilic, 4-hydroxybenzoic, phenylacetic, mandelic, pamoic, methanesulfonic, ethanesulfonic, benzenesulfonic, pantothenic, sulfanilic, stearic, alginic, trifluoromethanesulfonic, 2-hydroxyethanesulfonic, *p*-toluenesulfonic, cyclohexylaminosulfonic, β-hydroxybutyric, salicylic, galactaric and galacturonic, and any combinations thereof.

28. A use of at least one compound of claim 1 or a salt, solvate, enantiomer, diastereoisomer or tautomer thereof, in the manufacture of a medicament for preventing destabilization or stabilizing breathing rhythm in a subject in need thereof.

29. The use of claim 281, wherein the destabilization is associated with a breathing control disorder or disease selected from the group consisting of respiratory depression, sleep apnea, apnea of prematurity, obesity-hypoventilation syndrome, primary alveolar hypoventilation syndrome, dyspnea, altitude sickness, hypoxia, hypercapnia, chronic obstructive pulmonary disease (COPD), sudden infant death syndrome (SIDS), congenital central hypoventilation syndrome, Alzheimer's disease, Parkinson's disease, stroke, Duchenne muscular dystrophy, and brain and spinal cord traumatic injury.

30. The use of claim 29, wherein the respiratory depression is caused by an anesthetic, a sedative, a sleeping aid, an anxiolytic agent, a hypnotic agent, alcohol or a narcotic.

31. The use of claim 28, wherein the subject is further administered at least one agent useful for treating the breathing disorder or disease.

32. The use of claim 31, wherein the agent is selected from the group consisting of doxapram, acetazolamide, almitrine, theophylline, caffeine, methylprogesterone and related compounds, sedatives that increase arousal threshold in sleep disordered breathing patients, benzodiazepine receptor agonists, orexin antagonists, tricyclic antidepressants, serotonergic modulators, adenosine and adenosine receptor and nucleoside transporter modulators, cannabinoids, orexins, melatonin agonists, ampakines, sodium oxybate, modafinil, and armodafinil.

33. The use of claim 31, wherein the compound and the agent are separately administered to the subject.

34. The use of claim 31, wherein the compound and the agent are co-administered to the subject, further wherein the compound and the agent are physically mixed or physically separated when administered to the subject.

35. The use of claim 28, wherein the subject is further administered at least one additional therapeutic agent that changes normal breathing control in the subject.

36. The use of claim 35, wherein the additional agent is at least one selected from the group consisting of opioid narcotics, benzodiazepines, sedatives, sleeping aids, hypnotics, propofol, and any combinations thereof.

37. The use of claim 28, wherein the compound is administered in conjunction with the use of a mechanical ventilation device or positive airway pressure device on the subject.

38. The use of claim 28, wherein the subject is a mammal or bird.

39. The use of claim 28, wherein the compound is administered to the subject by at least one route selected from the group consisting of nasal, inhalational, topical, oral, buccal, rectal, pleural, peritoneal, vaginal, intramuscular, subcutaneous, transdermal, epidural, intrathecal and intravenous routes.

40. The use of claim 28, wherein the salt comprises an acid addition salt, and the acid is at least one selected from the group consisting of sulfuric, hydrochloric, hydrobromic, hydroiodic, nitric, carbonic, phosphoric, formic, acetic, propionic, succinic, glycolic, gluconic, lactic, malic, tartaric, citric, ascorbic, glucuronic, maleic, fumaric, pyruvic, aspartic, glutamic, benzoic, anthranilic, 4-hydroxybenzoic, phenylacetic, mandelic, pamoic, methanesulfonic, ethanesulfonic, benzenesulfonic, pantothenic, sulfanilic, stearic, alginic, trifluoromethanesulfonic, 2-hydroxyethanesulfonic, *p*-toluenesulfonic,

cyclohexylaminosulfonic, β-hydroxybutyric, salicylic, galactaric and galacturonic, and any combinations thereof.