UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): January 8, 2024

ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland	**001-35299**	**98-1007018**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Connaught House, 1 Burlington Road
Dublin 4, Ireland D04 C5Y6
(Address of principal executive offices)

Registrant's telephone number, including area code: + 353-1-772-8000

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Ordinary shares, $0.01 par value	ALKS	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On January 8, 2024, Alkermes plc made available a copy of the corporate presentation to be displayed during its presentation at the J.P. Morgan Healthcare Conference on January 10, 2024. A copy of the presentation is furnished herewith as Exhibit 99.1 and is incorporated by reference in this Item 7.01.

The information in this Item 7.01, and in Exhibit 99.1 furnished herewith, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

EXHIBIT INDEX

Exhibit No.	Description
99.1	Alkermes plc corporate presentation.
104	Cover page interactive data file (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALKERMES PLC

Date: January 8, 2024

By: /s/ David J. Gaffin
David J. Gaffin
Secretary

Exhibit 99.1

Alkermes 2024: Profitable, Pure-play Neuroscience Company

Richard Pops
Chief Executive Officer

42nd Annual J.P. Morgan Healthcare Conference
January 2024

Forward-Looking Statements

Certain statements set forth in this presentation constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: the company's expectations with respect to its current and future financial and operating performance, business plans or prospects, including its expected cash generation, revenue and growth drivers, expectations of profitability and potential return of capital to shareholders; the potential therapeutic and commercial value of the company's marketed products and development candidates; expectations regarding patent life for VUMERITY®; the company's expectations regarding plans and timelines for further clinical development activities, including for ALKS 2680, study timelines, design and dose selection; and the company's plans to advance and expand its neuroscience pipeline. The company cautions that forward-looking statements are inherently uncertain. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks, assumptions and uncertainties. These risks, assumptions and uncertainties include, among others: the unfavorable outcome of arbitration or litigation, including so-called "Paragraph IV" litigation or other patent litigation which may lead to competition from generic drug manufacturers, or other disputes related to the company's products or products using the company's proprietary technologies; the company's commercial activities may not result in the benefits that the company anticipates; clinical development activities may not be completed on time or at all; the results of the company's development activities, including those related to ALKS 2680, may not be positive, or predictive of final results from such activities, results of future development activities or real-world results; potential changes in the cost, scope, design or duration of the company's development activities; the U.S. Food and Drug Administration ("FDA") or other regulatory authorities may not agree with the company's regulatory approval strategies or components of the company's marketing applications and may make adverse decisions regarding the company's products; the company and its licensees may not be able to continue to successfully commercialize their products or support growth of such products; there may be a reduction in payment rate or reimbursement for the company's products or an increase in the company's financial obligations to government payers; the company's products may prove difficult to manufacture, be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; and those risks, assumptions and uncertainties described under the heading "Risk Factors" in the company's Annual Report on Form 10-K for the year ended Dec. 31, 2022 and in subsequent filings made by the company with the U.S. Securities and Exchange Commission ("SEC"), which are available on the SEC's website at www.sec.gov, and on the company's website at www.alkermes.com in the 'Investors – SEC filings' section. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this presentation.

Note Regarding Trademarks: The company and its affiliates are the owners of various U.S. federal trademark registrations (®) and other trademarks (™), including ARISTADA®, ARISTADA INITIO®, VIVITROL®, and LYBALVI®. INVEGA SUSTENNA® is a registered trademark of Johnson & Johnson or its affiliated companies. VUMERITY® is a registered trademark of Biogen MA Inc., used by Alkermes under license. Any other trademarks referred to in this presentation are the property of their respective owners. Appearances of such other trademarks herein should not be construed as any indicator that their respective owners will not assert their rights thereto.

Alkermes 2024: Profitable, Pure-play Neuroscience Company

*Based on revenues from VIVITROL®, ARISTADA®, VUMERITY® and LYBALVI® for twelve months ended Sept. 30, 2023

2023 Accomplishments Enabled Repositioning of Alkermes and Established Strong Foundation for Growth

- Prevailed in Janssen arbitration; Raised 2023 financial expectations
- Successfully settled VIVITROL® patent litigation
- Generated ALKS 2680 initial clinical proof-of-concept data in patients with narcolepsy type 1
- Completed separation of the oncology business
- Continued focus on operational efficiency including recent agreement to divest Athlone, Ireland manufacturing facility
- Grew proprietary commercial product portfolio net sales by 20%* year-over-year

*Based on nine months ended Sept. 30, 2023 compared to the same period in the prior year

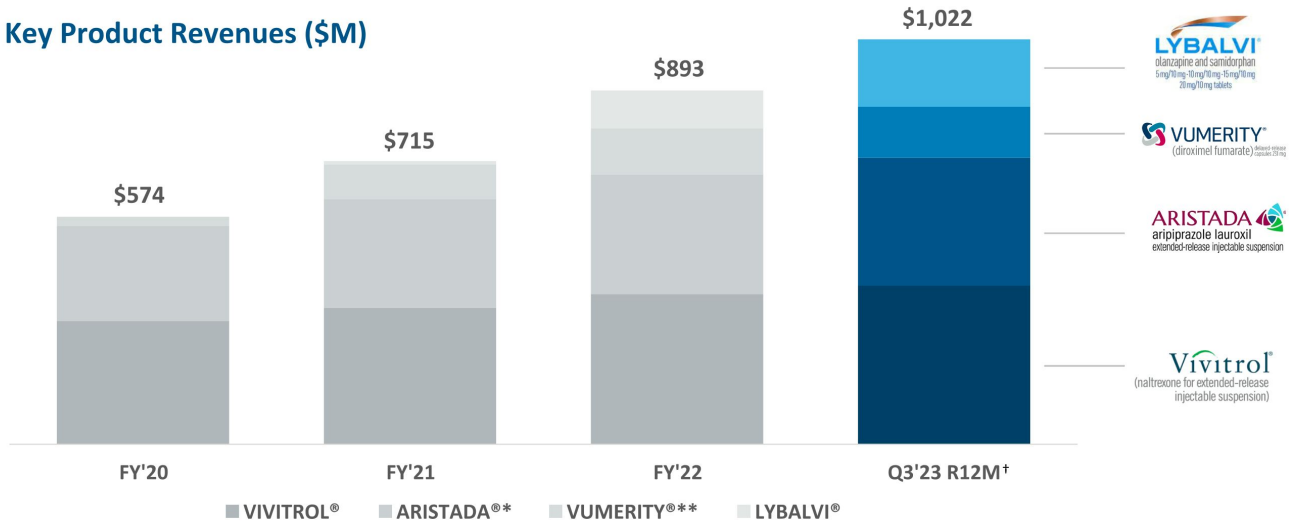
2024 Strategic Priorities

Deliver strong commercial growth and profitability	Driven by 4 core products and streamlined operating structure
Advance orexin 2 receptor agonist program	Initiate phase 2 program
Expand neuroscience pipeline	Advance internal development candidates and explore external pipeline opportunities
Plan for significant cash generation	Continue focus on capital allocation, including potential opportunities to return capital to shareholders

>$1B Commercial Business Primarily Driven by 4 Core Products

Topline Growth and Diversification Reflect Evolving Business

Key Product Revenues ($M)



*Inclusive of ARISTADA INITIO®
**Licensed product (royalty & manufacturing revenue)
†R12M = Rolling Twelve Months

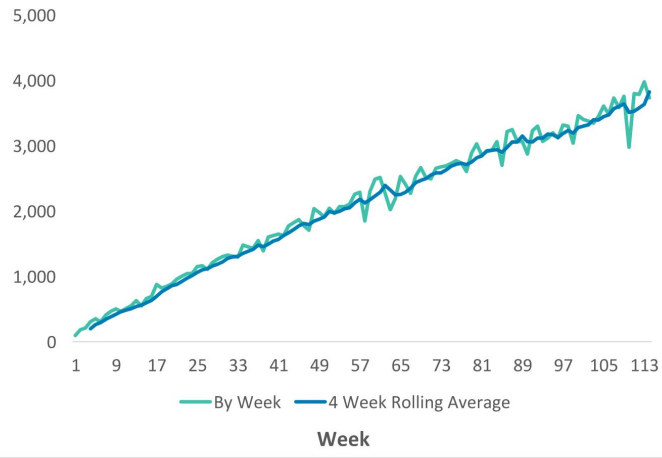
LYBALVI®: Oral Treatment Option for Schizophrenia and Bipolar I Disorder

- Once-daily, oral atypical antipsychotic composed of olanzapine, an established antipsychotic agent, and samidorphan, a new chemical entity
- Indicated for the treatment of:
  - Schizophrenia in adults
  - Bipolar I disorder in adults
    - Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate
    - Maintenance monotherapy treatment

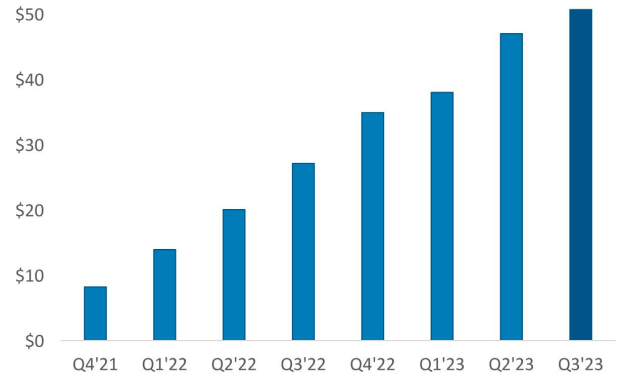
Full prescribing information for LYBALVI, including Boxed Warning, may be found at www.lybalvi.com/lybalvi-prescribing-information.pdf

LYBALVI® Launch Growth Trends

Post-Launch Weekly TRx*
(Through 12/22/2023)



LYBALVI Quarterly Net Sales ($M)



*Source: IQVIA NPA Weekly; IQVIA SOB Sep'23 R3M

LYBALVI®: Long-Term, Open-Label Extension Study Builds on Real World Experience*

Long-term treatment with LYBALVI for up to 4 years highlights its potential as a foundational treatment for appropriate patients with schizophrenia and bipolar I disorder

Stability of symptoms†	• Mean change in Clinical Global Impression of Severity (CGI-S) scale from baseline of -0.28
Minimal changes in body weight and waist circumference†	• Mean change in body weight from baseline of +1.47 kg and observed mean change in waist circumference from baseline of +0.61 cm
Minimal changes in lipid and glycemic parameters†	• Including HDL cholesterol, LDL cholesterol, triglycerides, fasting glucose, and HbA1c
Safety profile consistent with previous studies	• 60% of patients reported an adverse event (AE) • Most AEs were mild to moderate in severity • Most common AEs reported (>5%) were weight gain, headache, anxiety, insomnia, somnolence, nausea and weight decrease

Study Overview:

- Assessed the long-term safety, tolerability and durability of treatment effect of LYBALVI for up to 4 years
- 523 patients with schizophrenia, schizophreniform or bipolar I disorder who received at least one dose of LYBALVI
- 35.9% of patients completed 4 years of treatment

*For full press release announcing results https://investor.alkermes.com/news-releases/news-release-details/alkermes-announces-topline-results-long-term-open-label-safety
†Baseline based on 523 patients who completed a prior phase 3 trial with LYBALVI and who had enrolled in the study and received ≥1 dose of LYBALVI.
Changes compared to baseline based on patients who completed 4 years of open-label treatment.

ARISTADA®: LAI for the Treatment of Schizophrenia With Dosing Flexibility

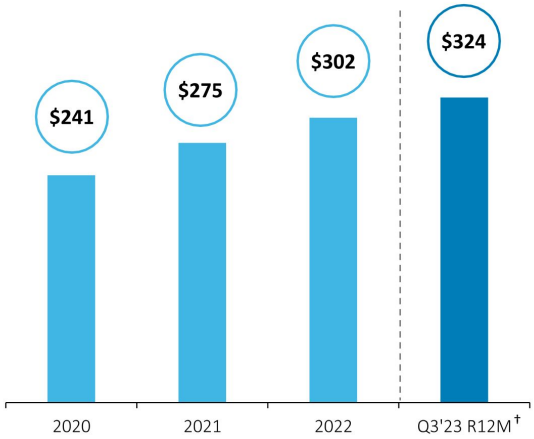
- Long-acting injectable (LAI) atypical antipsychotic indicated for the treatment of schizophrenia in adults
- Novel molecular entity designed to address the real-world needs of patients and providers
- Ability to fully dose on day one for up to two months with ARISTADA INITIO® regimen*

ARISTADA INITIO®
aripiprazole lauroxil
extended-release injectable suspension
675 mg

+

ARISTADA®
aripiprazole lauroxil
extended-release injectable suspension
441 mg | 662 mg | 882 mg | 1064 mg

ARISTADA Annual Net Sales ($M)**



*ARISTADA INITIO + single 30 mg oral dose of aripiprazole replaces need for concomitant three weeks of oral aripiprazole for initiation of ARISTADA. The first ARISTADA dose may be administered on the same day as ARISTADA INITIO or up to 10 days thereafter. Full prescribing information for ARISTADA, including Boxed Warning, may be found at www.aristada.com/downloadables/ARISTADA-PI.pdf

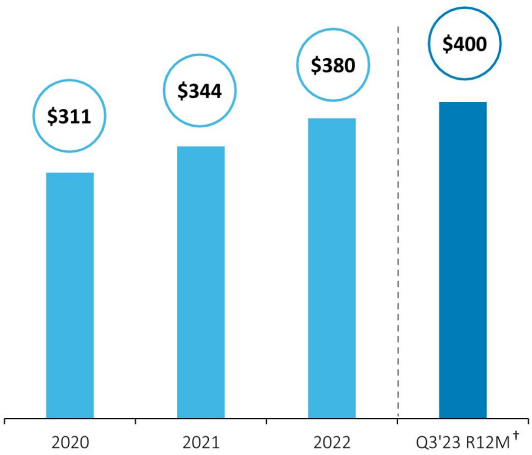
**Inclusive of ARISTADA INITIO®; †R12M = Rolling Twelve Months

VIVITROL®: LAI for the Treatment of Alcohol Dependence and Opioid Dependence

- Extended-release opioid antagonist provides therapeutic levels of naltrexone for a one-month period
- Indicated for the treatment of alcohol dependence (AD) in patients able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL
- Indicated for the prevention of relapse to opioid dependence (OD), following opioid detoxification

Vivitrol®
(naltrexone for extended-release injectable suspension) 380 mg/vial

VIVITROL Annual Net Sales ($M)



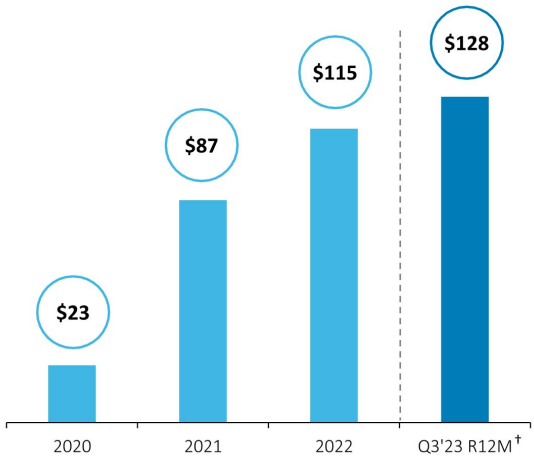
Full prescribing information for VIVITROL may be found at www.vivitrol.com/content/pdfs/prescribing-information.pdf.
Treatment with VIVITROL should be part of a comprehensive management program that includes psychosocial support.
†R12M = Rolling Twelve Months

VUMERITY® Offers Long-Term Revenue Growth Opportunity

- Novel oral fumarate for the treatment of relapsing forms of multiple sclerosis (MS)
- Biogen holds exclusive, worldwide license to commercialize
- 15% royalty to Alkermes on worldwide net sales
- Discovered and developed by Alkermes
- Composition of matter patent extends into 2033*

VUMERITY® (diroximel fumarate) delayed-release capsules 231 mg

VUMERITY Royalty & Manufacturing Revenue ($M)



*Subject to Paragraph IV litigation related to an abbreviated new drug application seeking FDA approval of a generic version.

†R12M = Rolling Twelve Months

Proven Drug Development Capabilities with Advancing Neuroscience Pipeline

Proven Neuroscience Drug Development Capabilities

Neuroscience drug development expertise has yielded multiple commercial products:

Vivitrol® (naltrexone for extended-release injectable suspension) 380 mg/vial

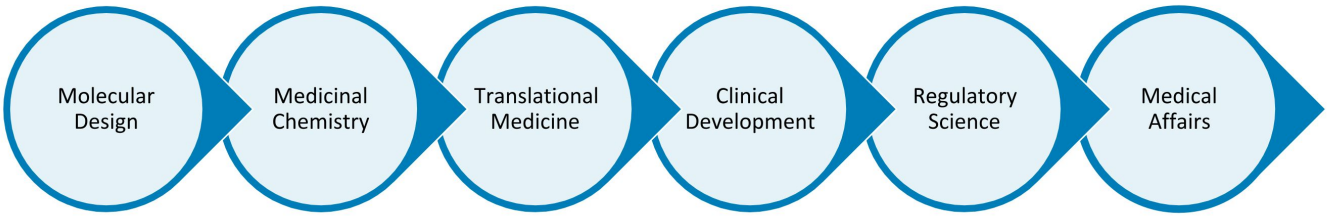
ARISTADA INITIO® aripiprazole lauroxil extended-release injectable suspension 675 mg

ARISTADA® aripiprazole lauroxil extended-release injectable suspension 441 mg 662 mg 882 mg 1064 mg

LYBALVI® olanzapine and samidorphan 5 mg/10 mg · 10 mg/10 mg · 15 mg/10 mg 20 mg/10 mg tablets

VUMERITY® (diroximel fumarate) delayed-release capsules 231 mg

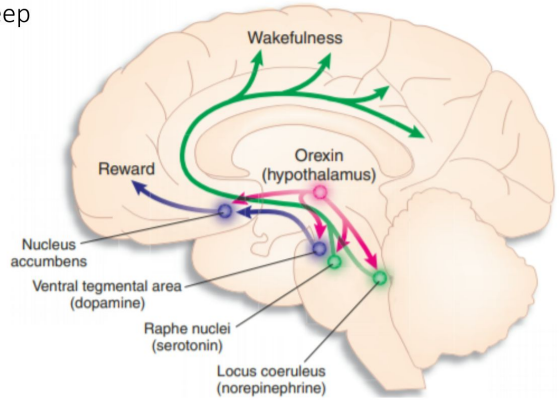
Enabled by established capabilities in:



VUMERITY is licensed to and commercialized exclusively by Biogen

Orexin Dysfunction: Well Defined Opportunity in Narcolepsy and Other Sleep Disorders

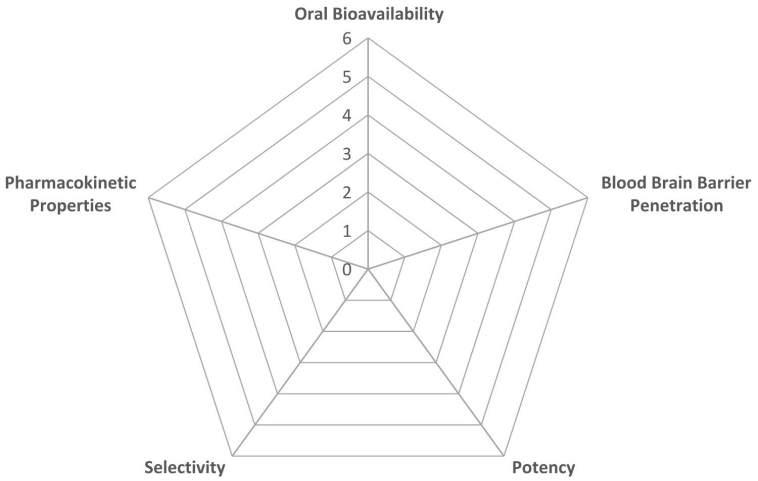
- In narcolepsy, low orexin levels lead to inconsistent neurotransmitter release, resulting in excessive sleepiness and poor regulation of REM sleep
- Narcolepsy (types 1 and 2) affects ~200,000 people in U.S. and 3M people globally[1]
- 70% of people with narcolepsy have narcolepsy type 1[2] (NT1), distinguished by:
  - Cataplexy, a sudden muscle weakness triggered by strong emotions
  - Low or no orexin in the brain
- People with narcolepsy type 2 experience excessive daytime sleepiness but not cataplexy and generally have normal levels of orexin
- Genetic and pharmacologic evidence suggests that orexin receptor agonists, especially OX2R agonists, may be useful for mechanistic therapy of narcolepsy[3]



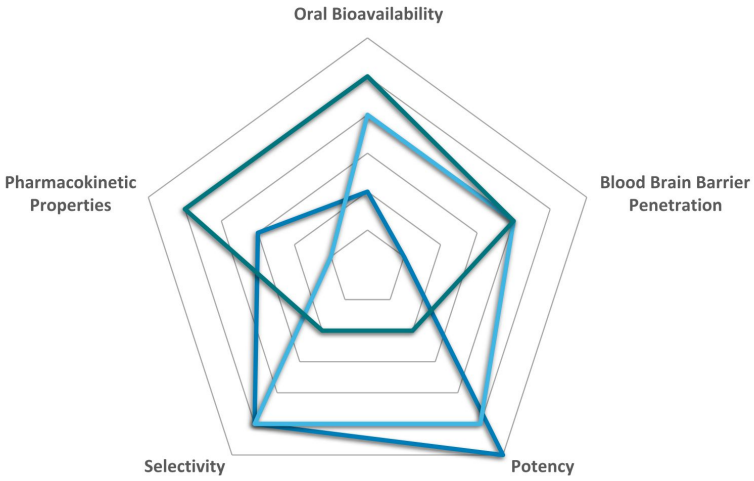
[1] Global Narcolepsy Drugs Market, Forecast 2019-2025. Allied Market Research
[2] Swick TJ. Treatment paradigms for cataplexy in narcolepsy: past, present, and future. *Nat Sci Sleep*. 2015;7:159-169
[3] Nagahara T. Design and Synthesis of Non-Peptide, Selective Orexin Receptor 2 Agonists. *J. Med. Chem.* 2015;58:7931–7937
OX2R: orexin 2 receptor

Figure from: Scammell, T E, and Saper, C B. *Nature medicine*. 2007;13:126-8

OX2R: Molecular Design Challenge and Optimization Parameters

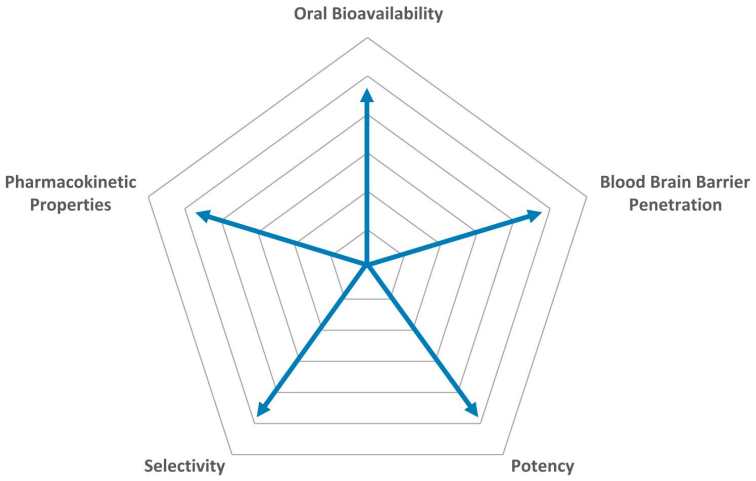


OX2R: Molecular Design Challenge and Optimization Parameters



Potential pharmaceutical profiles are for illustrative purposes only and do not represent any specific development candidate

OX2R: Molecular Design Challenge and Optimization Parameters



Potential pharmaceutical profiles are for illustrative purposes only and do not represent any specific development candidate

ALKS 2680

Investigational oral orexin 2 receptor agonist for the treatment of narcolepsy designed for:

- Improved wakefulness duration and quality
- PK/PD profile that mirrors natural sleep/wake cycle
- Cataplexy control
- Low therapeutic dose with once-daily oral dosing
- Acceptable safety profile with wide therapeutic window

ALKS 2680: Investigational Oral Orexin 2 Receptor Agonist for the Treatment of Narcolepsy

ALKS 2680 is a highly potent, selective OX2R agonist

- ≥10 fold more potent than orexin A[a]
- >5,000-fold selectivity relative to OX1R[a]

ALKS 2680 initial phase 1 data demonstrated desired pharmaceutical properties:

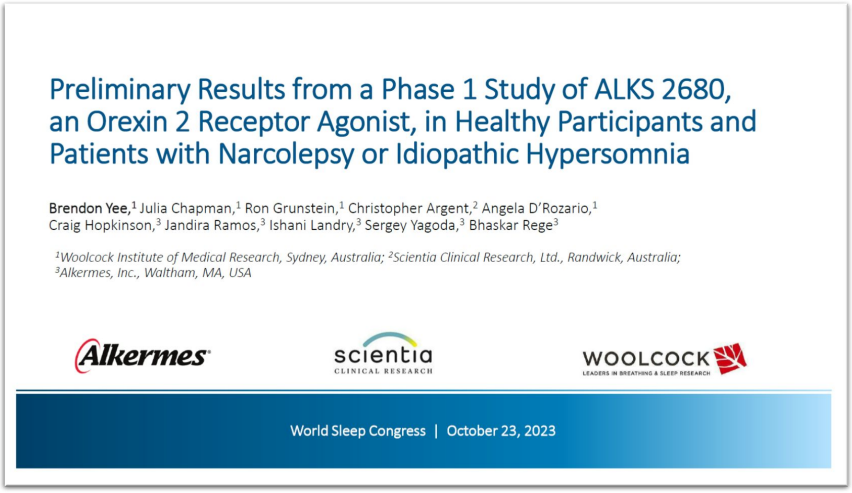
- Orally bioavailable
- PK profile supportive of once-daily dosing
- Mimics natural sleep/wake cycle
- Half life of 8-10 hours

Program Status

- ☐ Phase 1b proof-of-concept study underway
  - ✓ Recently completed phase 1b NT1 cohort
  - ✓ Phase 2 NT1 doses selected
  - ☐ Phase 1b NT2 and IH proof-of-concept data expected H1 2024
  - ☐ Phase 2 NT2 dose selection
- ☐ Phase 2 NT1 study initiation expected H1 2024

[a]Data from preclinical studies using CHO (Chinese hamster ovary) cells.
OX1R: orexin 1 receptor; OX2R: orexin 2 receptor; PK: pharmacokinetic; NT1: narcolepsy type 1; NT2: narcolepsy type 2; IH: idiopathic hypersomnia

ALKS 2680: First-in-Human Data Presented at 2023 World Sleep Meeting



- Single- and multiple-ascending dose study safety and tolerability data (n=80)
- Initial proof-of-concept data in patients with Narcolepsy Type 1 (n=4)

October 20-25 WORLD SLEEP 2023 Rio de Janeiro BRAZIL

ALKS 2680: Results From Full NT1 (n=10) Cohort Support Advancement to Phase 2

Efficacy

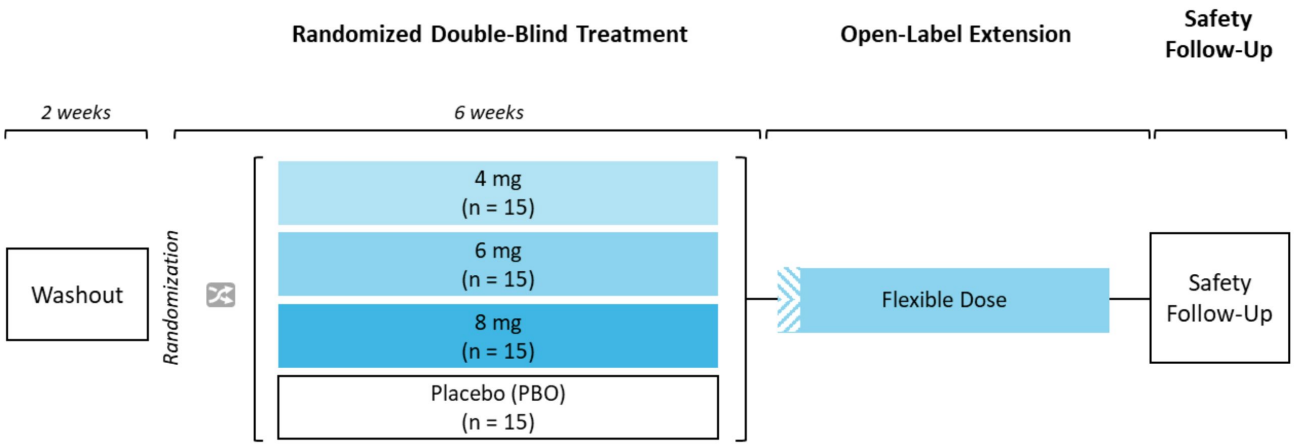
- Statistically significant and clinically meaningful improvement of maintenance of wakefulness test (MWT) scores at each dose level (1 mg, 3 mg, 8 mg)
- Dose-dependent magnitude and durability of effect
- Dose range for phase 2 selected
  - 4 mg, 6 mg, and 8 mg
  - Dose range designed to accommodate expected and observed heterogeneity in baseline sleep latency scores and responses
  - Administered once daily in the morning

Safety and Tolerability

- Generally well tolerated at all doses tested
- Treatment-emergent adverse events (TEAEs) were transient, self-resolving and mild in severity, with one moderate case of nausea which resolved with food intake
  - No serious AEs or AEs leading to discontinuation
- AEs generally consistent with initial four NT1 subjects
  - New drug-related TEAEs included nausea, decreased appetite and elevated heart rate
  - No occurrence of treatment-emergent liver enzyme elevations
  - No occurrence of visual disturbances
- No drug-related, treatment-emergent, clinically meaningful changes in laboratory parameters or adverse changes in ECGs

ALKS 2680: Advancing Into Phase 2 in 2024

Planned Narcolepsy Type 1 Phase 2 Design



Phase 2 Designed to Capture Standard Endpoints and Exploratory Measures

Planned Primary and Secondary Assessments

- Maintenance of Wakefulness Test (MWT)
  - Change from baseline in average sleep latency on MWT over 8 hours
  - 40-minute EEG-based test administered every two hours
- Epworth Sleepiness Scale
  - Widely used in field of sleep medicine as subjective measure of sleepiness
  - List of eight situations in which patients rate tendency to become sleepy on scale of 0 (no chance of dozing), to 3 (high chance of dozing); total score based on scale of 0 to 24
- Weekly cataplexy rates
  - Captured in patient diaries

Key Exploratory Measures

- Patient reported outcomes
  - Focused on quality of wakefulness and overall quality of life
- Nighttime polysomnography
  - Measures of sleep architecture and quality
- Actigraphy and sleep diaries

Building a Neuroscience Development Pipeline That Leverages Alkermes' Capabilities

R&D Framework

- Strong biological rationale
- Challenging molecular design
- Clear clinical pathway with early proof-of-concept
- Aligns with Alkermes' expertise
- Advances standard of care

Orexin 2 pathway activation
- Narcolepsy
- Other excessive daytime sleepiness disorders
- Other neuropsychiatric disorders

Other internal neuroscience candidates
- Psychiatry and neurology
- Chemistry and preclinical evaluation underway

Potential externally-sourced pipeline candidates

Positioned for Sustained Profitability and Significant Cash Generation

Commercial Performance and Efficient Cost Structure Expected to Drive Meaningful Profitability

2024 Key Financial Expectations:

Revenues

- Continued growth of proprietary commercial products revenue
- INVEGA SUSTENNA® U.S. royalty expiration in August 2024

Operating Expenses

- R&D expense savings of ~$150M compared to 2023 following separation of oncology business in November 2023

Balance Sheet

- Starting 2024 with ~$800M in cash and investments
- Sale of Athlone manufacturing facility expected to close mid-year
  - Entitled to a one-time cash payment of $92.5 million† for the facility and related assets
  - Expected to be operating cost neutral in 2024

Key 2024 Financial Metrics **

>$1B Proprietary product net sales

~30% EBITDA margin*

*The company is not providing reconciliations of, or comparable measures prepared in accordance with generally accepted accounting principles in the U.S. ("GAAP") for, forward-looking non-GAAP profitability measures because the comparable GAAP measures are not determinable without unreasonable efforts due to the inherent difficulty in forecasting and quantifying certain future financial amounts necessary for such reconciliations, which amounts could have a significant impact on the company's future financial results, including the comparable GAAP financial measures.

† Aggregate purchase price and closing date subject to adjustments and certain closing conditions, respectively.

**These expectations were provided by the Company on Jan. 8, 2024 and are effective only as of such date. The Company expressly disclaims any obligation to update or reaffirm these expectations.

EBITDA: Earnings before interest, tax, depreciation, amortization; earnings include share-based compensation expense.

2024 Strategic Priorities

Deliver strong commercial growth and profitability	Driven by 4 core products and streamlined operating structure
Advance orexin 2 receptor agonist program	Initiate phase 2 program
Expand neuroscience pipeline	Advance internal development candidates and explore external pipeline opportunities
Plan for significant cash generation	Continue focus on capital allocation, including potential opportunities to return capital to shareholders

www.alkermes.com