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): December 2, 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 December 2, 2024, Alkermes plc made available a copy of its updated corporate presentation. A copy of the presentation is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

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, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be 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: December 2, 2024

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

Exhibit 99.1

Alkermes 2024: Profitable, Pure-play Neuroscience Company

December 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 and profitability, capital allocation strategy, revenue and growth drivers, potential transactional opportunities and return of capital to shareholders; the potential therapeutic and commercial value of the company's marketed products and development candidates; expectations regarding the patent life for VUMERITY® and generic competition for VIVITROL®; the company's plans and expectations regarding clinical development activities, including study timelines and design for ALKS 2680, and strategy and timelines for the company's other orexin portfolio candidates; 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: whether the company is able to sustain profitability; 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, 2023 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®, LYBALVI® and VIVITROL®. 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 Dec. 31, 2023

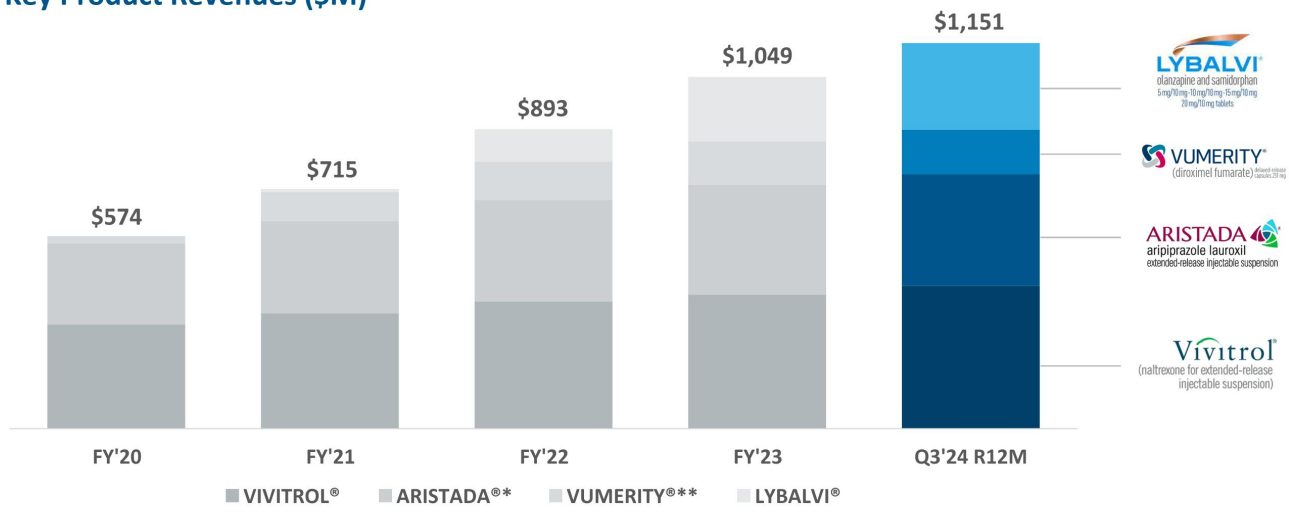
2024 Strategic Priorities

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 12 Months

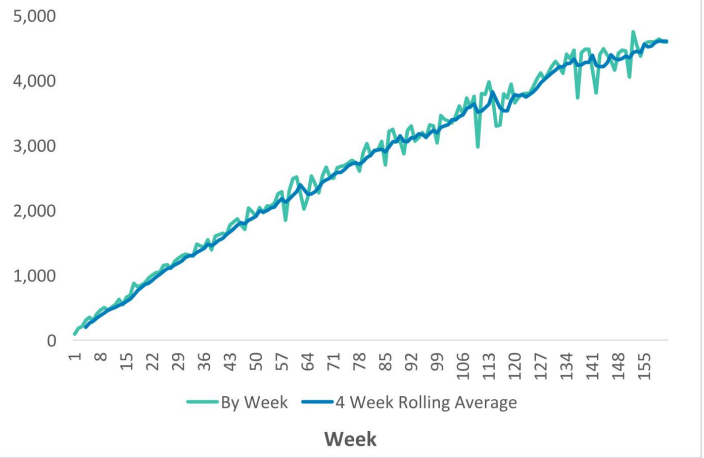
LYBALVI®: Oral Treatment Option for Schizophrenia and Bipolar I Disorder

- 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
    - M[illegible]ance[illegible]other[illegible]eatm[illegible]

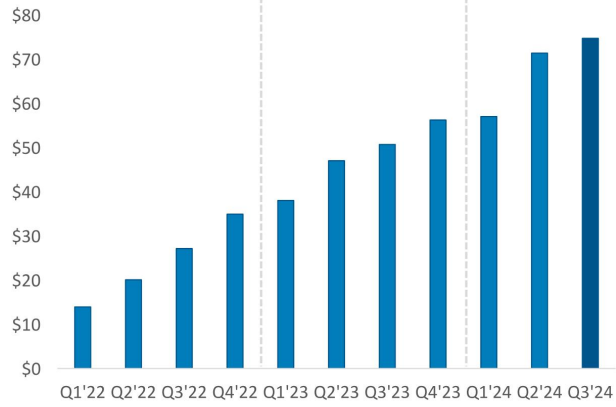
Full prescribing information for LYBALVI, including Boxed Warning, may be found at www.lybalvi.com/lybalvi-prescribing-information.pdf

LYBALVI® Launch Growth Trends

Post-Launch Weekly TRx*
(Through 11/15/2024)



LYBALVI Quarterly Net Sales ($M)



*Source: IQVIA NPA Weekly

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

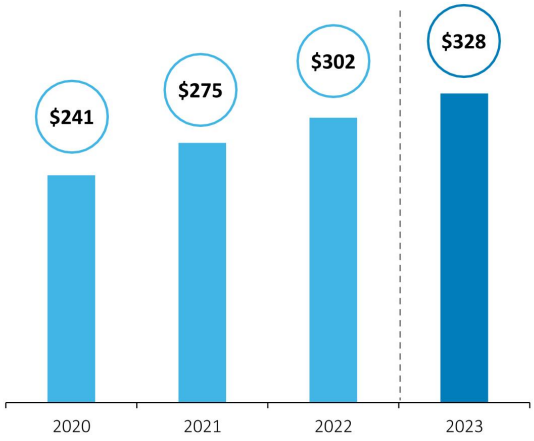
- Long-acting injectable (LAI) atypical antipsychotic indicated for the treatment of schizophrenia in adults
- Novel molecular entity designed to address the real-world needs of patients and providers
- Ability to fully dose on day one for up to two months with ARISTADA INITIO® regimen*

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)**



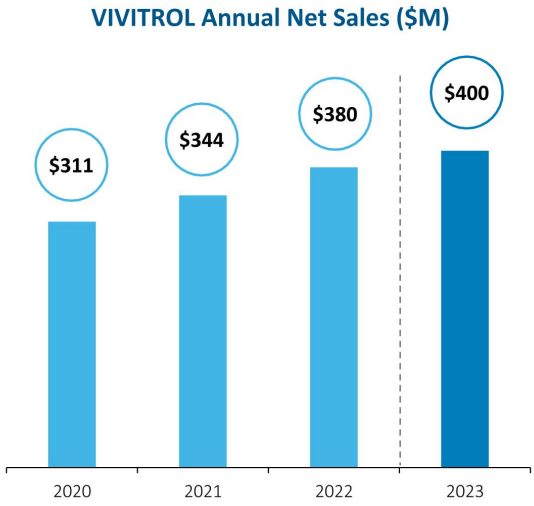
*ARISTADA INITIO + single 30 mg oral dose of aripiprazole replaces need for concomitant three weeks of oral aripiprazole for initiation of ARISTADA. The first ARISTADA dose may be administered on the same day as ARISTADA INITIO or up to 10 days thereafter. Full prescribing information for ARISTADA, including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

**Inclusive of ARISTADA INITIO®

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
- Generics expected to enter the market under license from Alkermes in January 2027 or earlier under certain circumstances

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



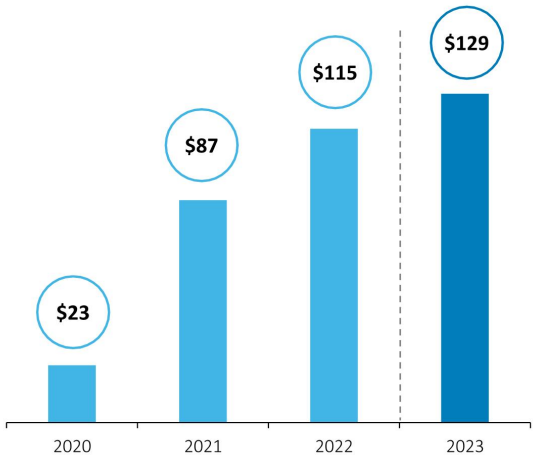
Full prescribing information for VIVITROL may be found at www.vivitrol.com/content/pdfs/prescribing-information.pdf.
Treatment with VIVITROL should be part of a comprehensive management program that includes psychosocial support.

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.

Proven Drug Development Capabilities with Advancing Neuroscience Pipeline

Symptom Commonality Across Sleep Disorders Results in Diagnostic Challenges

Common Symptoms in Narcolepsy Type 1, Narcolepsy Type 2 and Idiopathic Hypersomnia

Symptoms	NT1	NT2	IH
Excessive daytime sleepiness (EDS)			
Sleep-onset REM periods (SOREMP)			
Cataplexy			
Disrupted nighttime sleep			
Needed naps: short, refreshing			
Sleep-related hallucinations			
Sleep paralysis			
Brain fog			
Long sleep			
Severe sleep inertia			
Needed naps: long, unrefreshing			

Almost always (90 to 100% of people with this disorder have this symptom)
More common (41 to 89% of people with this disorder have this symptom)
Less common (11 to 40% of people with this disorder have this symptom)
Rare (0 to 10% of people with this disorder have this symptom)

www.hypersomniafoundation.org/classification/; Sateia MJ. International classification of sleep disorders-third edition: highlights and modifications. *Chest*. 2014;146:1387–94.; Rassu, Evangelista, Barateau, et al. *J Clin Sleep Medicine*. 2022, 617-629.
NT1: Narcolepsy type 1; NT2: Narcolepsy type 2; IH: Idiopathic hypersomnia; REM: rapid eye movement

Narcolepsy and Idiopathic Hypersomnia in the U.S.

Narcolepsy prevalence **200,000**[a]

100,000 diagnosed[b]

Idiopathic Hypersomnia

40,000 diagnosed[c]

[a]Narcolepsy Network Fast Facts
[b]Cohen et al., *Sleep Med* 43:14 (2018) and Longstreth et al., *Sleep Med* 10:422 (2009) prevalence rates applied to U.S. population
[c]Acquavella et al., *J Clin Sleep Med* 16:1255 (2020)

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

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 phase 1 data demonstrated desired pharmaceutical properties:

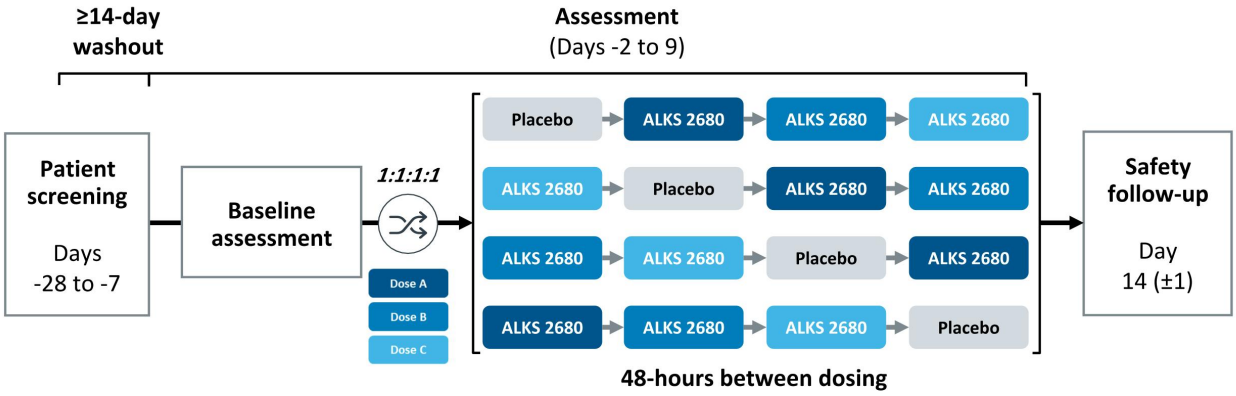
- Orally bioavailable
- PK profile supportive of once-daily dosing
- Mimics natural sleep/wake cycle

2024 Clinical Program Status

- Phase 1 single ascending dose and multiple ascending dose study complete
- Phase 1b proof-of-concept study complete
- Vibrance-1 phase 2 NT1 study enrolling
- Vibrance-2 phase 2 NT2 study enrolling
- Vibrance-3 phase 2 IH study planning underway
- Open-label, long-term safety study expected to initiate in Q4 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 Phase 1b: Randomized, Double-Blind, PBO-Controlled Study in Patients With NT1, NT2 and IH Provides Proof-of-Concept



- Patients had a confirmed diagnosis with no baseline criteria for MWT
- Key objectives:
  - Safety and tolerability
  - Mean sleep latency on Maintenance of Wakefulness Test (MWT) at baseline and each day of dosing

Patient Population	n	ALKS 2680 Doses
NT1	10	1, 3 & 8 mg
NT2	9	5, 12 & 25 mg
IH	8	5, 12 & 25 mg

PBO: Placebo; NT1: Narcolepsy type 1; NT2: Narcolepsy type 2; IH: Idiopathic hypersomnia

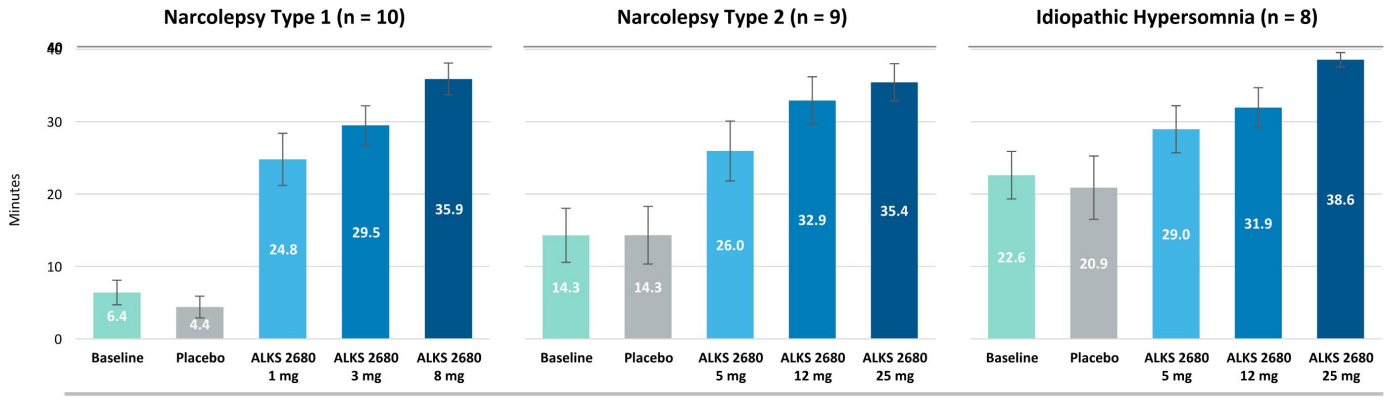
ALKS 2680 Phase 1b: Generally Well-Tolerated at all Doses Tested in NT1, NT2 and IH

- Most TEAEs were mild in severity and transient
- No deaths, serious TEAEs, severe TEAEs, or TEAEs leading to discontinuation
- Treatment-related TEAEs* reported in >1 subject in each population listed below:
  - NT1: insomnia, pollakiuria, salivary hypersecretion, decreased appetite, dizziness, and nausea
  - NT2: pollakiuria, insomnia, and dizziness
  - IH: pollakiuria, insomnia, and dizziness
- No clinically meaningful changes in laboratory parameters
- No cardiovascular safety signals in vital signs or ECGs

*Relationship per investigator determination.
Insomnia includes TEAE terms of insomnia, middle insomnia, and initial insomnia. Dizziness includes TEAE terms of dizziness and dizziness postural.
NT1: Narcolepsy type 1; NT2: Narcolepsy type 2; IH: Idiopathic hypersomnia; TEAE: Treatment-Emergent Adverse Event; ECG: Electrocardiogram

ALKS 2680 Phase 1b: Demonstrated Meaningful, Consistent and Dose-Dependent Effect on Wakefulness in NT1, NT2 & IH Patients

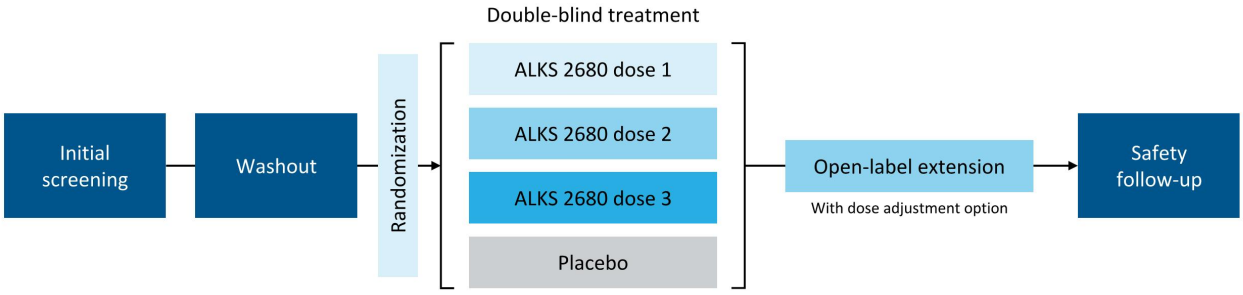
Absolute Mean Sleep Latency on Maintenance of Wakefulness Test (MWT) - Mean± SE



Primary Analysis		ALKS 2680 1 mg	ALKS 2680 3 mg	ALKS 2680 8 mg	ALKS 2680 5 mg	ALKS 2680 12 mg	ALKS 2680 25 mg	ALKS 2680 5 mg	ALKS 2680 12 mg	ALKS 2680 25 mg
	LS mean (95% CI) difference vs placebo[1]	18.38 (10.95, 28.80)	22.57 (15.56,29.58)	33.97 (26.72,41.21)	11.60 (2.22, 20.98)	18.55 (9.17, 27.93)	20.96 (11.58, 30.34)	8.07 (0.06, 16.07)	11.05 (3.04, 19.05)	17.67 (9.67, 25.68)
	p-value	**0.0002**	**0.0001**	**<0.0001**	**0.0178**	**0.0005**	**0.0001**	**0.0484**	**0.0096**	**0.0002**

1: Primary analysis based on a mixed effect model of repeated measurement with the dose level and the period as fixed factors, and the average sleep latency on Day -1 is included as the baseline covariate
SE: standard error; LS: least squares

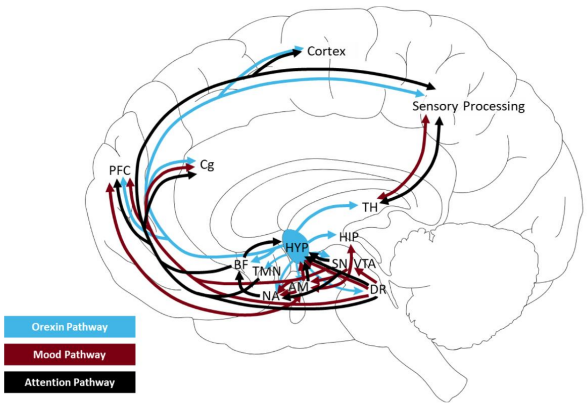
ALKS 2680 Phase 2 Clinical Program Evaluating Once-Daily Administration Across a Range of Patient Populations



Study	n	ALKS 2680 Doses	Screening Period		Double-blind Treatment Period	Open-label Extension Period	Follow-up Period	Primary Endpoint
			Initial	Washout				
Narcolepsy Type 1 VIBRANCE-1	80	4, 6 & 8 mg	≤ 4-weeks	2-weeks	6-weeks	7-weeks	2-weeks	Δ MWT at week 6
Narcolepsy Type 2 VIBRANCE-2	80	10, 14 & 18 mg	≤ 4-weeks	2-weeks	8-weeks	5-weeks	2-weeks	Δ MWT at week 8
Idiopathic Hypersomnia VIBRANCE-3	Study design in progress							

MWT: Maintenance of Wakefulness Test; Δ: change from baseline

Orexin 2 Receptor Agonist Pathway May Have Potential Applicability in Broad Range of Indications



AM: amygdala; BF: basal forebrain; Cg: cingulate cortex; DR: dorsal raphe; HIP: hippocampus; HYP: hypothalamus; NA: nucleus accumbens; PFC: prefrontal cortex; SN: substantia nigra; TH: thalamus; TMN: tuberomammillary nucleus; VTA: ventral tegmental area.

Select disease states which intersect across aspects of wakefulness, fatigue, mood and cognition

Neurology

- Attention-deficit/hyperactivity disorder
- Multiple sclerosis fatigue
- Parkinson's disease

Psychiatry

- Bipolar disorder
- Cognitive impairment in schizophrenia
- Negative symptoms of schizophrenia
- Major depressive disorder
- Seasonal affective disorder

Orphan/ultra-orphan disorders

Advancing Multiple Orexin Development Candidates for Treatment of Neurology & Psychiatry Disorders

Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Next Planned Milestone
ALKS 2680					
Narcolepsy Type 1					Phase 2 data H2 2025
Narcolepsy Type 2					Phase 2 data H2 2025
Idiopathic Hypersomnia					Phase 2 initiation 2025
Project Saturn: Additional OX2R molecules expected to enter the clinic in 2025					
					Phase 1 initiation Mid-2025
					Phase 1 initiation H2 2025

OX2R: Orexin 2 receptor agonist

Positioned for Robust Profitability and Significant Cash Generation

Commercial Performance and Efficient Cost Structure Expected to Drive Meaningful Profitability

- >$1B commercial business driven primarily by 4 core products*
- Positioned for sustained profitability and significant cash generation
- Ended 2023 with $813M in cash and investments

*Based on revenues from VIVITROL®, ARISTADA®, VUMERITY® and LYBALVI® for twelve months ended Dec. 31, 2023

Capital Allocation Strategy

Maximize the potential of proprietary commercial products with primary focus on LYBALVI®

Invest in internal development pipeline to advance new neuroscience candidates

Pursue external opportunities to expand portfolio with assets that are a strong strategic fit

Return excess cash to shareholders

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