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News & Events

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Viking Therapeutics Reports Fourth Quarter and Year-End 2024 Financial Results and Provides Corporate Update

Conference call scheduled for 4:30 p.m. ET today

- **Initiation of Phase 3 Studies for Subcutaneous VK2735 for Obesity Planned for 2Q25**
- **Phase 2 VENTURE-Oral Dosing Trial Evaluating VK2735 in Obesity Underway**
- **Strong Year-End Cash Position of $903 Million**

SAN DIEGO, Feb. 5, 2025 /PRNewswire (http://www.prnewswire.com/)/ -- Viking Therapeutics, Inc. ("Viking") (NASDAQ: VKTX), a clinical-stage biopharmaceutical company focused on the development of novel therapies for metabolic and endocrine disorders, today announced its financial results for the fourth quarter and year ended December 31, 2024, and provided an update on its clinical pipeline and other corporate developments.

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Highlights from the Quarter and Year Ended December 31, 2024, and Other Recent Events:

"2024 was an exciting and extremely productive year for Viking," stated Brian Lian, Ph.D., chief executive officer of Viking. "During the year, the company reported positive data from four different clinical trials, including results from the Phase 2 VENTURE study of subcutaneous VK2735 for obesity, the Phase 1 study of an oral tablet formulation of VK2735 for obesity, the Phase 2b VOYAGE study of VK2809 for the treatment of MASH and fibrosis, and the Phase 1b study of VK0214 for X-ALD. Each of these studies successfully achieved their objectives with each in our view demonstrating best-in-class data. During the year, the company also announced a new pipeline program focused on novel internally developed dual agonists of the amylin and calcitonin receptors. In preclinical models, these compounds demonstrated impressive reductions in body weight and improvement in metabolic profiles. We look forward to advancing this program into clinical development later this year. On the corporate side, Viking completed the year with a strong balance sheet, with over $900 million in cash and equivalents, providing the resources to achieve important clinical goals, including the completion of Phase 3 trials for VK2735 in obesity."

Pipeline and Recent Corporate Highlights

- **Initiation of Phase 3 Studies for Subcutaneous VK2735 for Obesity Planned for 2Q25.** VK2735 is a wholly owned dual agonist of the glucagon like peptide-1, or GLP-1 receptor, and the glucose dependent insulinotropic polypeptide, or GIP receptor, for the potential treatment of obesity and other metabolic disorders.

  In early 2024, Viking announced positive top-line results from its Phase 2 VENTURE study of VK2735 in obesity. The VENTURE trial successfully achieved its primary and all secondary endpoints, with patients receiving VK2735 demonstrating clinically meaningful reductions in body weight compared with placebo. With respect to the primary endpoint after 13 weekly doses, patients receiving VK2735 demonstrated statistically significant reductions in mean body weight from baseline, ranging up to 14.7%, as well as statistically significant reductions in mean body weight relative to placebo, ranging up to 13.1%. Differences compared to placebo were statistically significant for all doses starting at Week 1 and were maintained through the course of the study. In addition, results from follow-up visits that occurred four and seven weeks after the last dose of VK2735 was administered showed that cohorts receiving VK2735 maintained the majority of their weight loss through the seven week follow-up visit after administration of the final dose.

  VK2735 also demonstrated encouraging safety and tolerability in the VENTURE study, with the majority of observed adverse events (AEs) being reported as mild or moderate. Treatment and study discontinuation rates among VK2735 cohorts were well-balanced compared with placebo. Of gastrointestinal (GI) related AEs, 95% were reported as mild or

moderate. Across all cohorts in the VENTURE study, GI-related AEs were most prevalent during the first week of treatment, with observed rates generally declining through the remainder of the study. The results of the VENTURE study were presented at ObesityWeek®, the annual meeting of The Obesity Society, in November 2024.

In the fourth quarter of 2024, the company completed an End-of-Phase 2 meeting with the FDA and received feedback on the proposed Phase 3 plans as well as the overall development program for VK2735. The company expects to initiate Phase 3 trials evaluating subcutaneous VK2735 in obesity in 2Q25.

- **Phase 2 VENTURE-Oral Dosing Trial Evaluating VK2735 in Obesity Underway.** Concurrent with the development of a subcutaneous formulation, Viking is also developing an oral tablet formulation of VK2735, which the company believes could represent an attractive treatment option for patients who are hesitant to initiate injection-based therapy, or for those seeking to maintain the weight loss they have already achieved. A differentiating feature of the tablet formulation of VK2735 is that it offers the potential to transition patients from the subcutaneous formulation to an oral formulation which utilizes the same molecule. Viking believes this may reduce the risk of unexpected safety or tolerability challenges, and could be an appealing option for both patients and clinicians.

  During the first quarter of 2024, Viking reported the initial results from a Phase 1 multiple ascending dose trial evaluating oral VK2735. This trial was a randomized, double-blind, placebo-controlled Phase 1 trial in healthy adults with a minimum BMI of 30 kg/m^2, evaluating once-daily oral doses ranging from 2.5 mg to 100 mg. The primary objective of the study was to evaluate the safety and tolerability of VK2735 administered as an oral tablet once daily for 28 days. The secondary objective was to evaluate the pharmacokinetics of orally administered VK2735 in healthy subjects. Exploratory pharmacodynamic measures included assessments of changes in body weight and other metrics.

  Viking presented the final Phase 1 study results in November at ObesityWeek 2024. The results showed that cohorts receiving VK2735 demonstrated dose-dependent reductions in mean body weight from baseline, ranging up to 8.2%. Persistent weight loss effects were observed at follow-up visits through Day 57, four weeks after the last dose of VK2735 was administered. Weight loss at Day 57 ranged up to 8.3% from baseline. An exploratory assessment of the proportion of subjects in each cohort achieving at least 5% weight loss after 28 days demonstrated that up to 100% of VK2735-treated subjects achieved ≥5% weight loss, compared with 0% for placebo. Based on a preliminary evaluation of weight loss trajectories at multiple dose levels, the company believes that continued treatment beyond 28 days may provide further reductions in body weight.

  Oral VK2735 also demonstrated encouraging safety and tolerability through 28 days of once-daily dosing at doses up to and including 100 mg. The majority of observed treatment emergent adverse events were mild or moderate, with the majority reported as mild. Similarly, all observed GI-related AEs were reported as mild or moderate, with the majority reported as mild.

  Based on these promising results, Viking recently announced the initiation of a 13-week Phase 2a trial to evaluate longer term dosing with the tablet formulation of VK2735 in obese subjects. This trial, called the VENTURE-Oral Dosing trial, is a randomized, double-blind, placebo-controlled multicenter study designed to evaluate the safety, tolerability, pharmacokinetics and weight loss efficacy of VK2735 dosed as an oral tablet once daily for 13 weeks. The trial will enroll approximately 280 adults who are obese, or adults who are overweight with at least one weight-related co-morbid condition. Patients will be evenly randomized to one of six dosing arms or placebo. The primary endpoint of the study is the percent change in body weight from baseline after 13 weeks of treatment. Secondary and exploratory endpoints will evaluate a range of additional safety and efficacy measures. The company expects to report data from this study in 2H25.

- **Best-in-Class Data from Phase 2b VOYAGE Trial in MASH Highlighted in Oral Late Breaker Presentation at The Liver Meeting® 2024.** VK2809 is an orally available, small molecule agonist of the thyroid hormone receptor that is selective for liver tissue, as well as the beta isoform of the receptor.

  In 2024, the company announced completion of the Phase 2b VOYAGE study, an international trial designed to assess the efficacy, safety and tolerability of VK2809 in patients with biopsy-confirmed metabolic dysfunction associated steatohepatitis (MASH) and fibrosis following 52 weeks of dosing. The primary endpoint of the study evaluated the change in liver fat from baseline to Week 12 in patients treated with VK2809 compared to patients receiving placebo. Secondary and exploratory endpoints assessed histologic changes, such as MASH resolution and fibrosis improvement, following 52 weeks of treatment.

  In 2023, the company reported that VOYAGE had successfully achieved its primary endpoint, with patients receiving VK2809 demonstrating statistically significant reductions in liver fat content from baseline to Week 12 as compared with placebo. The median relative change from baseline in liver fat among patients treated with VK2809 ranged from 38% to 55% after 12 weeks. In addition, up to 85% of patients receiving VK2809 experienced at least a 30% relative reduction in liver fat.

  In the second quarter of 2024, Viking announced the initial histology results from the VOYAGE study, demonstrating the successful achievement of the trial's secondary endpoints assessed by hepatic biopsy after 52 weeks of treatment. Patients receiving VK2809 demonstrated statistically significant improvements in MASH resolution rate, fibrosis stage, and the combination endpoint of MASH resolution and fibrosis improvement. On the endpoint of MASH resolution without worsening of fibrosis, VK2809-treated patients demonstrated resolution rates ranging from 63% to 75%, compared with 29% for placebo. On the secondary endpoint evaluating the proportion of patients demonstrating at least a one stage improvement in fibrosis with no worsening of MASH, the proportion of VK2809-treated patients achieving this endpoint ranged from 44% to 57%, compared with 34% for placebo. And, on the secondary endpoint evaluating the proportion of patients experiencing both the resolution of MASH and at least a one-stage improvement in fibrosis, the proportion of VK2809-treated patients achieving both measures ranged from 40% to 50%, compared with 20% for placebo.

  As observed in prior studies, patients receiving VK2809 in VOYAGE demonstrated statistically significant improvements in plasma lipids. Placebo-adjusted reductions in low-density lipoprotein cholesterol (LDL-C) ranged from 20% to 25%, and reductions in triglycerides and atherogenic proteins such as apolipoprotein B, lipoprotein (a), and apolipoprotein C-III, were also significantly improved relative to placebo. These lipids have been correlated with cardiovascular risk, suggesting that treatment with VK2809 may offer a long-term cardio-protective benefit.

  VK2809 also demonstrated an encouraging safety and tolerability profile through 52 weeks of treatment, with minimal differences compared with the previously reported results from 12 weeks. The majority, 94%, of treatment related adverse events among patients receiving VK2809 were reported as mild or moderate. Discontinuations due to adverse events were low and balanced across placebo and treatment arms. VK2809 demonstrated excellent GI tolerability through 52 weeks of treatment, with similar rates of nausea, diarrhea, stool frequency, and vomiting among VK2809-treated patients as compared to placebo.

  In November 2024, the company reported final results from the VOYAGE study in an oral late breaker presentation at The Liver Meeting®, the annual meeting of the American Association for the Study of Liver Disease, or AASLD. The company believes these data affirm VK2809's best-in-class efficacy on both MASH resolution and fibrosis improvement, along with the potential for cardiovascular benefit through improvement in plasma lipids. The company is currently evaluating potential next steps with VK2809.

- **Phase 1b Study Evaluating VK0214 in X-ALD Demonstrates Improvement in Key Biomarker.** VK0214 is a novel, orally available thyroid hormone receptor beta agonist that is being evaluated as a potential treatment for X-linked adrenoleukodystrophy (X-ALD), a rare neurogenerative disease for which there are currently no pharmacologic treatment options. Like VK2809, VK0214 is also an orally available small molecule that is selective for the beta isoform of the thyroid hormone receptor.

  X-ALD is a debilitating metabolic disorder that is caused by genetic mutations that disable the function of a peroxisomal transporter of very long chain fatty acids (VLCFAs). As a result, patients are unable to efficiently metabolize these acids, and their accumulation is believed to contribute to the onset and progression of X-ALD. Activation of the thyroid hormone receptor beta has been shown to increase the expression of an important compensatory VLCFA transporter, leading to improved metabolism and clearance of these compounds.

In the fourth quarter of 2024, Viking reported the results from a 28-day Phase 1b study of its small molecule drug candidate VK0214 in patients with X-ALD. The trial enrolled patients across three cohorts: placebo, and VK0214 doses of 20 mg and 40 mg daily. The primary objectives of the Phase 1b study were to evaluate the safety and tolerability of VK0214 in subjects with the adrenomyeloneuropathy (AMN) form of X-ALD, which is the most common form of the disease. An exploratory objective was to evaluate the effects of VK0214 on plasma levels of VLCFAs in this population. The results of this study showed that treatment with VK0214 resulted in significant reductions in mean VLCFA levels at both the 20 mg and 40 mg doses, compared to placebo. Plasma levels of the important 26 carbon very long chain fatty acid, a diagnostic biomarker, were reduced by approximately 38% relative to placebo ($p<0.05$).

In addition, subjects who received VK0214 experienced reductions in other important plasma lipids. Mean reductions relative to baseline and placebo were observed for LDL-C, apolipoprotein B, and lipoprotein (a) following 28 days of treatment. Importantly, VK0214 also demonstrated encouraging safety and tolerability, with treatment emergent adverse events generally reported as mild to moderate. The company plans to explore partnering opportunities for the further development of VK0214.

- **Dual Amylin and Calcitonin Receptor Agonist (DACRA) Program Ongoing; IND Planned for 2025.** The amylin receptor plays an important role in food intake and metabolic control, making it an attractive potential target for therapeutic intervention in obesity. Viking is evaluating an internally developed dual amylin and calcitonin receptor agonist (DACRA) program for the potential treatment of obesity.

  During the second quarter of 2024, Viking presented in vivo data from this program at the American Diabetes Association's (ADA's) Annual Scientific Sessions. The company's presentation highlighted the effects of treatment on body weight, food intake and metabolic profile in both healthy rats and in diet-induced obese mice. The results demonstrated that Viking's dual amylin and calcitonin receptor agonists reduced food intake in lean rats in the period from 0 – 72 hours following a single subcutaneous dose.

  Based on these promising data, Viking is currently planning to file an IND application for this program later this year.

- **Upcoming Investor Events.** Viking management will participate in the following upcoming investor events:

  Oppenheimer 35th Annual Healthcare Life Sciences Conference
  Virtual
  February 11 – 12, 2025

  Leerink Partners Global Healthcare Conference
  Miami Beach, FL
  March 10 – 12, 2025

  Jefferies Biotech on the Beach Summit
  Miami Beach, FL
  March 11 – 12, 2025

  24th Annual Needham Healthcare Conference
  Virtual
  April 7 – 10, 2025

Fourth Quarter and Full-Year 2024 Financial Highlights

Fourth Quarter ended December 31, 2024 and 2023

Research and development expenses were $31.0 million for the three months ended December 31, 2024, compared to $20.5 million for the same period in 2023. The increase was primarily due to increased expenses related to manufacturing for the company's drug candidates, salaries and benefits and stock-based compensation, partially offset by decreased expenses related to clinical studies and preclinical studies.

General and administrative expenses were $15.3 million for the three months ended December 31, 2024, compared to $8.8 million for the same period in 2023. The increase was primarily due to increased expenses related to legal and patent services, stock-based compensation, salaries and benefits, insurance and professional fees.

For the three months ended December 31, 2024, Viking reported a net loss of $35.4 million, or $0.32 per share, compared to a net loss of $24.6 million, or $0.25 per share, in the corresponding period in 2023. The increase in net loss for the three months ended December 31, 2024, was primarily due to the increase in research and development expenses and general and administrative expenses, noted previously, partially offset by increased interest income, compared to the same period in 2023.

Year Ended December 31, 2024 and 2023

Research and development expenses for the year ended December 31, 2024, were $101.6 million compared to $63.8 million for the same period in 2023. The increase was primarily due to increased expenses related to manufacturing for the company's drug candidates, stock-based compensation and salaries and benefits, partially offset by a decrease in expenses related to clinical studies and preclinical studies.

General and administrative expenses for the year ended December 31, 2024, were $49.3 million compared to $37.0 million for the same period in 2023. The increase was primarily due to increased expenses related to stock-based compensation, salaries and benefits, professional fees, insurance and services provided by third-party consultants, partially offset by decreased expenses related to legal and patent services.

For the year ended December 31, 2024, Viking reported a net loss of $110.0 million, or $1.01 per share, compared to a net loss of $85.9 million, or $0.91 per share, in the corresponding period in 2023. The increase in net loss for the year ended December 31, 2024, was primarily due to the increase in research and development expenses and general and administrative expenses, noted previously, partially offset by increased interest income, compared to the same period in 2023.

Balance Sheet as of December 31, 2024

At December 31, 2024, Viking held cash, cash equivalents and short-term investments of $903 million, compared to $362 million as of December 31, 2023.

Conference Call

Management will host a conference call to discuss Viking's fourth quarter and full-year 2024 financial results today at 4:30 pm Eastern. To participate in the conference call, please dial (844) 850-0543 from the U.S. or (412) 317-5199 from outside the U.S. In addition, following the completion of the call, a telephone replay will be accessible until February 12, 2025, by dialing (877) 344-7529 from the U.S. or (412) 317-0088 from outside the U.S. and entering conference ID #6731266. Those interested in listening to the conference call live via the internet may do so by visiting the Webcasts page of Viking's website at http://ir.vikingtherapeutics.com/webcasts (https://c212.net/c/link/?t=0&l=en&o=4356195-1&h=866593733&u=http%3A%2F%2Fir.vikingtherapeutics.com%2Fwebcasts&a=http%3A%2F%2Fir.vikingtherapeutics.com%2Fwebcasts). An archive of the webcast will also be available on the Webcasts page of Viking's website for 30 days.

About Viking Therapeutics, Inc.

Viking Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the development of novel first-in-class or best-in-class therapies for the treatment of metabolic and endocrine disorders, with three compounds currently in clinical trials. Viking's research and development activities leverage its expertise in metabolism to develop innovative therapeutics designed to improve patients' lives. Viking's clinical programs include VK2735, a novel dual agonist of the glucagon-like peptide 1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP) receptors for the potential treatment of various metabolic disorders. Data from a Phase 1 and a Phase 2 trial evaluating VK2735 (dosed subcutaneously) for metabolic disorders demonstrated an encouraging safety and tolerability profile as well as positive signs of clinical benefit. Concurrently, the company is evaluating an oral formulation of VK2735 in a Phase 2 trial. Viking is also developing VK2809, a novel, orally available, small molecule selective thyroid hormone receptor beta agonist for the treatment of lipid and metabolic disorders. The compound successfully achieved both the primary and secondary endpoints in a recently completed Phase 2b study for the treatment of biopsy-confirmed non-alcoholic steatohepatitis (NASH) and fibrosis. In a Phase 2a trial for the treatment of non-alcoholic fatty liver disease (NAFLD) and elevated LDL-C, patients who received VK2809 demonstrated statistically significant reductions in LDL-C and liver fat content compared with patients who received placebo. The company's newest program is evaluating a series of internally developed dual amylin and calcitonin receptor agonists (or DACRAs) for the treatment of obesity and other metabolic disorders. In the rare disease space, Viking is developing VK0214, a novel, orally available, small molecule selective thyroid hormone receptor beta agonist for the potential treatment of X-linked adrenoleukodystrophy (X-ALD). In a Phase 1b clinical trial in patients with the adrenomyeloneuropathy (AMN) form of X-ALD, VK0214 was shown to be safe and well-tolerated, while driving significant reductions in plasma levels of very long-chain fatty acids (VLCFAs) and other lipids, as compared to placebo.

For more information about Viking Therapeutics, please visit www.vikingtherapeutics.com (https://c212.net/c/link/?t=0&l=en&o=4356195-1&h=3780184989&u=https%3A%2F%2Fc212.net%2Fc%2Flink%2F%3Ft%3D0%26l%3Den%26o%3D4335959-1%26h%3D2155840703%26u%3Dhttps%253A%252F%252Fwww.vikingtherapeutics.com%252F%26a%3Dwww.vikingtherapeutics.com&a=www.vikingt

Forward-Looking Statements

This press release contains forward-looking statements regarding Viking Therapeutics, Inc., under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including statements about Viking's expectations regarding its clinical and preclinical development programs, anticipated timing for reporting clinical data and cash resources. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and adversely and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: risks associated with the success, cost and timing of Viking's product candidate development activities and clinical trials, including those for VK2735, VK0214, VK2809, and the company's other incretin receptor agonists; risks that prior clinical and preclinical results may not be replicated; risks regarding regulatory requirements; and other risks that are described in Viking's most recent periodic reports filed with the Securities and Exchange Commission including Viking's Annual Report on Form 10-K for the year ended December 31, 2024, and subsequent Quarterly Reports on Form 10-Q, including the risk factors set forth in those filings. These forward-looking statements speak only as of the date hereof. Viking disclaims any obligation to update these forward-looking statements except as required by law.

Viking Therapeutics, Inc. Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except per share amounts) (Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
Revenues	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	30,987	20,502	101,644	63,806
General and administrative	15,251	8,783	49,277	37,021
Total operating expenses	46,238	29,285	150,921	100,827
Loss from operations	(46,238)	(29,285)	(150,921)	(100,827)
Other income (expense):				
Amortization of financing costs	(24)	(26)	(94)	(88)
Interest income, net	10,844	4,706	40,940	15,020
Realized gain on investments, net	1	—	112	—
Total other income, net	10,821	4,680	40,958	14,932
Net loss	(35,417)	(24,605)	(109,963)	(85,895)

Other comprehensive loss, net of tax:				
Unrealized (loss) gain on securities	(2,252)	437	173	742
Foreign currency translation (loss) gain	(168)	79	(226)	(29)
Comprehensive loss	$ (37,837)	$ (24,089)	$ (110,362)	$ (85,182)
Basic and diluted net loss per share	$ (0.32)	$ (0.25)	$ (1.01)	$ (0.91)
Weighted-average shares used to compute basic and diluted net loss per share	111,344	99,884	109,037	94,347

Viking Therapeutics, Inc. Consolidated Balance Sheets

(In thousands, except share and per share amounts)
(Unaudited)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 26,676	$ 55,516
Short-term investments – available-for-sale	875,936	306,563
Prepaid clinical trial and preclinical study costs	3,476	2,624
Prepaid expenses and other current assets	1,128	2,522
Total current assets	907,216	367,225
Right-of-use assets	1,003	1,126
Deferred financing costs	56	106
Deposits	46	33
Total assets	$ 908,321	$ 368,490
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,813	$ 7,512
Other accrued liabilities	17,111	11,299
Lease liability, current	489	324
Total current liabilities	27,413	19,135
Lease liability, net of current portion	630	936
Total long-term liabilities	630	936
Total liabilities	28,043	20,071
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.00001 par value: 10,000,000 shares authorized at December 31, 2024 and 2023; no shares issued and outstanding at December 31, 2024 and 2023	—	—
Common stock, $0.00001 par value: 300,000,000 shares authorized at December 31, 2024 and 2023; 111,573,519 shares issued and outstanding at December 31, 2024 and 100,113,770 shares issued and outstanding at December 31, 2023	1	1
Treasury stock at cost, no shares at December 31, 2024 and 2,193,251 shares at December 31, 2023	—	(6,795)
Additional paid-in capital	1,368,972	733,546
Accumulated deficit	(487,907)	(377,944)
Accumulated other comprehensive loss	(788)	(389)
Total stockholders' equity	880,278	348,419
Total liabilities and stockholders' equity	$ 908,321	$ 368,490

SOURCE Viking Therapeutics, Inc.

For further information: Contacts: Viking Therapeutics, Greg Zante, Chief Financial Officer, 858-704-4672, gzante@vikingtherapeutics.com; Vida Strategic Partners, Stephanie Diaz (Investors), 415-675-7401, sdiaz@vidasp.com; Tim Brons (Media), 415-675-7402, tbrons@vidasp.com

(http://www.vikingtherapeutics.com/)

ABOUT

Viking Therapeutics is developing novel therapeutics for patients suffering from metabolic and endocrine disorders.

CONTACT

General Information (mailto:info@vikingtherapeutics.com)
Business Development (mailto:BD@vikingtherapeutics.com)

Terms of Use (http://www.vikingtherapeutics.com/terms-of-use/)
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