

**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**

June 5, 2024 (May 31, 2024)
Date of Report (date of earliest event reported)

LUMOS PHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

001-35342
(Commission File Number)

42-1491350
(I.R.S. Employer Identification No.)

4200 Marathon Blvd., Suite 200
Austin, Texas 78756
(Address of Principal Executive Offices)
(512) 215-2630
Registrant's telephone number, including area code

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
Common Stock	LUMO	The Nasdaq Stock 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 5.07 Submission of Matters to a Vote of Security Holders.

The 2024 Annual Meeting of Stockholders (the "2024 Annual Meeting") of Lumos Pharma, Inc. (the "Company") was held May 31, 2024, for the following purposes:

- To elect the nominees for director, Chad A. Johnson and Lota S. Zoth, nominated by the Board of Directors of the Company (the "Board"), to serve until the 2027 Annual Meeting of Stockholders;
- To approve, on a non-binding, advisory basis, the compensation of the Company's named executive officers as disclosed in the Company's definitive proxy statement, filed with the Securities and Exchange Commission on April 12, 2024 (the "Proxy Statement");
- To select, on a non-binding, advisory basis, the frequency of how often the approval of the compensation of our named executive officers will be presented to our stockholders; and
- To ratify the selection by the Audit Committee of the Board of KPMG, LLP as the independent registered public accounting firm of the Company for its fiscal year ending December 31, 2024.

At the meeting, the stockholders of the Company:

- elected Chad A. Johnson and Lota S. Zoth as directors of the Company;
- approved, on a non-binding, advisory basis, the compensation of the Company's named executive officers, as set forth in the Proxy Statement;
- approved, on a non-binding, advisory basis, the frequency of every one year for the frequency of future advisory votes on the compensation of the Company's named executive officers; and
- ratified the appointment of KPMG, LLP as the Company's independent registered public accounting firm for the Company's fiscal year ending December 31, 2024.

The final voting results on each of the matters submitted to a vote of stockholders at the 2024 Annual Meeting are as follows:

Election of Directors		For	Withheld	Broker Non-Votes
1.	Chad A. Johnson	3,531,517	544,327	2,434,840
	Lota S. Zoth	4,055,737	20,107	2,434,840

		For	Against	Abstentions	Broker Non-Votes
2.	Approval, on an advisory basis, of the compensation of the Company's named executive officers	3,590,994	29,097	455,753	2,434,840

		1 year	2 years	3 years	Abstentions	Broker Non-Votes
3.	Approval, on an advisory basis, of the frequency of future advisory votes on the compensation of the Company's named executive officers	3,278,561	6,685	335,737	454,861	2,434,840

Based on these results and the recommendation of the Board in the Proxy Statement for the 2024 Annual Meeting, the Company will conduct an advisory vote on the compensation of its named executive officers once every year until such time as the next advisory vote on the preferred frequency of advisory votes on executive compensation is submitted to stockholders.

		For	Against	Abstentions
4.	Ratification of KPMG, LLP as independent registered public accounting firm for the Company's fiscal year ending December 31, 2024	6,050,515	457,802	2,367

Item 7.01 Regulation FD Disclosure.

On June 4, 2024, the Company issued a press release titled "Lumos Pharma Announces New Analyses of Phase 2 OraGrowthH212 Trial Presented at ENDO 2024."

A copy of the press release and an updated corporate slide deck are attached hereto as Exhibit 99.1 and Exhibit 99.2 and are incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1 and Exhibit 99.2 incorporated by reference herein shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section. This information shall not be deemed to be 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 Number	Description
99.1	Press Release, dated June 4, 2024, titled " Lumos Pharma Announces New Analyses of Phase 2 OraGrowH212 Trial Presented at ENDO 2024. "
99.2	Corporate Slide Deck
104	Cover Page Interactive Data File (formatted as Inline XBRL)

SIGNATURES

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.

Dated: June 5, 2024

LUMOS PHARMA, INC.,
a Delaware corporation

By: /s/ Richard J. Hawkins
Richard J. Hawkins
Its: Chief Executive Officer

Lumos Pharma Announces New Analyses of Phase 2

OraGrowthH212 Trial Presented at ENDO 2024

AUSTIN, TX, June 4, 2024 (GLOBE NEWSWIRE) – [Lumos Pharma, Inc.](#) (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, announced today details of new analyses of data from its Phase 2 OraGrowthH212 clinical trial presented in two posters at the [2024 Annual Meeting of the Endocrine Society \(ENDO\)](#), held in Boston, MA, June 1-4, 2024. The posters were presented in parallel sessions on Monday June 3, 2024.

“The new analyses of data from our OraGrowthH212 Trial further characterized LUM-201’s unique ability to augment the natural pulsatile secretion of growth hormone, producing comparable growth to injectable rhGH with significantly less exposure to circulating growth hormone,” said John C. McKew, PhD, President and Chief Scientific Officer of Lumos Pharma. “The presented results also provide additional support for our planned approach to a placebo-controlled Phase 3 trial of LUM-201 in moderate PGHD, a trial design proposed by the FDA as an appropriate option for oral LUM-201 given its differentiated mechanism as a growth hormone secretagogue.”

In the poster MON-111, titled, *Oral LUM-201 Restores Pulsatile Growth Hormone Secretion and Growth Response in Moderate Pediatric Growth Hormone Deficiency (PGHD): Key Discoveries from Phase 2 of OraGrowthH212 Trial* (Cassorla, F, et al) [[poster link](#)], investigators evaluated growth hormone pulsatility data obtained at baseline and at six months following treatment with LUM-201.

- Results showed that at six months on LUM-201, a significant increase over baseline in key parameters was observed for the 1.6 mg/kg/day dose. At baseline GH secretion was 0.19 ± 0.09 $\mu\text{g/kg/12-hrs}$; pulsatile GH was 1.17 ± 0.66 $\mu\text{g/kg/12-hrs}$; and total GH was 1.35 ± 0.66 $\mu\text{g/kg/12-hrs}$.
- At 6 months each parameter increased significantly: GH secretion to 0.36 ± 0.21 $\mu\text{g/kg/12-hrs}$, pulsatile GH to 1.8 ± 0.74 $\mu\text{g/kg/12-hrs}$, and total GH to 2.2 ± 0.89 $\mu\text{g/kg/12-hrs}$
- A similar level of increase was observed in the 3.2 mg/kg/day dose cohort
- Investigators combined data from both dose cohorts and conducted a deconvolution analysis on GH secretion. It was determined that at six months GH secretion was 3.3 ± 1.8 to 4.4 ± 2.1 $\mu\text{g/kg/day}$ compared to 5.0 ± 1.3 $\mu\text{g/kg/day}$ derived from published data in normal children, indicating restoration of approximately normal GH secretion by LUM-201.
- Conclusion – at 6 months LUM-201 was able to restore endogenous GH pulsatile secretion to a similar level seen in normal children while also normalizing serum IGF-1 concentrations. Results indicate that by restoring endogenous GH secretion, LUM-201 facilitates growth utilizing a much lower amount of GH than that provided by daily exogenous rhGH. By providing an oral therapy that attains physiological GH profiles, investigational LUM-201 treatment aligns with the fundamental objectives of endocrine therapies, specifically the restoration of normal hormonal homeostasis.

In a late-breaking poster (MON-704) titled, *Growth Response to Oral Growth Hormone Secretagogue LUM-201 in Children with Moderate GH Deficiency (GHD) is Dependent on the Pattern of Pulsatile GH Secretion Stimulated by LUM-201* (Stevens, A, et al), [[poster link](#)], investigators evaluated pulsatile GH profiles and growth response to LUM-201.

- Data from OraGrowthH212 pulse assessments at Day 1 (D1) and at 6 months (M6) were analyzed utilizing a univariate Spearman’s rank correlations matrix to screen for relationships between D1 characteristics, D1 height velocity, 6M Annualized Height Velocity and interpulse, pulsatile, and total GH secretion at D1 and M6.
- The 12-hour pattern of pulsatile secretion was characterized using Functional Principal Component Analysis (FPCA) to identify dominant modes of variation in the functional data. Subjects were grouped into tertiles based on 6M AHV. The 12-hour profiles were grouped into three 4-hour intervals.
- Results:
 - All parameters increased from D1 to M6
 - D1 pulsatile GH secretion was positively associated with D1 AHV
 - While 6M AHV increased compared to baseline, GH Secretion at D1 and M6 was not apparently correlated with 6M AHV

- In the FPCA, difference in interquartile range (IQR) for mean GH secretion was highest in 0-4 hrs in subjects in the high and medium AHV tertiles, while subjects with low AHV at 6 months had the highest difference at 8-12 hours
- Conclusions – LUM-201 stimulates significant increases in GH secretion over 6 months in patients with moderate PGHD. The relationship between growth response and both the amount and pattern of pulsatile GH secretion, with the highest growth observed in OraGrowthH212 associated with greatest pulsatile activity early in the 12 hour profile. Restoring GH secretion with LUM-201 in moderate PGHD results in both an increase in the overall amount of GH, and importantly, an alteration of the pattern of the pulse profile, with distinct differences in these patterns between the best and lower responders.

About Lumos Pharma

Lumos Pharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of therapeutics for rare diseases. The Company was founded and is led by a management team with longstanding experience in rare disease drug development. Lumos Pharma's lead therapeutic candidate, LUM-201, is a novel, oral growth hormone (GH) secretagogue, seeking to transform the ~\$4.7B global GH market from injectable to oral therapy. LUM-201 is currently being evaluated in multiple Phase 2 clinical studies in Pediatric Growth Hormone Deficiency (PGHD) and has received Orphan Drug Designation in both the US and EU. For more information, please visit <https://lumos-pharma.com/>.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of Lumos Pharma, Inc. that involve substantial risks and uncertainties. All such statements contained in this press release are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. A law that, in part, gives us the opportunity to share our outlook for the future without fear of litigation if it turns out our predictions were not correct.

We are passionate about our business - including LUM-201 and the potential it may have to help patients in the clinic. This passion feeds our optimism that our efforts will be successful and bring about meaningful change for patients. Please keep in mind that actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make.

We have attempted to identify forward-looking statements by using words such as "projected," "upcoming," "will," "would," "plan," "intend," "anticipate," "approximate," "expect," "potential," "imminent," and similar references to future periods or the negative of these terms. Not all forward-looking statements contain these identifying words. Examples of forward-looking statements include, among others, statements we make regarding the advancement of oral LUM-201 to Phase 3, the potential for LUM-201 to be the first oral therapeutic for PGHD, and any other statements other than statements of historical fact.

We wish we were able to predict the future with 100% accuracy, but that just is not possible. Our forward-looking statements are neither historical facts nor assurances of future performance. You should not rely on any of these forward-looking statements and, to help you make your own risk determinations, we have provided an extensive discussion of risks that could cause actual results to differ materially from our forward-looking statements including risks related to the timing and ability of Lumos Pharma to structure our Phase 3 trial in an effective and timely manner, the ability to initiate and advance a pivotal Phase 3 trial, as well as advance our clinical and corporate strategy in general, our ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the ability to successfully develop our product candidate, the effects of pandemics, other widespread health problems or military conflicts including the Ukraine-Russia conflict and the Middle East conflict and other risks that could cause actual results to differ materially from those matters expressed in or implied by such forward-looking statements including information in the "Risk Factors" section and elsewhere in Lumos Pharma's Quarterly Report on Form 10-Q for the period ended September 30, 2023, as well as other subsequent reports filed with the SEC. All of these documents are available on our website. Before making any decisions concerning our stock, you should read and understand those documents.

We anticipate that subsequent events and developments will cause our views to change. We may choose to update these forward-looking statements at some point in the future, however, we disclaim any obligation to do so. As a result, you should not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

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Investor & Media Contact:

Lisa Miller
Lumos Pharma Investor Relations
512-792-5454
lr@lumos-pharma.com



Source: Lumos Pharma, Inc.



Transforming Lives with Rare Focus

Corporate & Clinical Overview

May 2024

Forward Looking Statements

This presentation contains forward-looking statements of Lumos Pharma, Inc. that involve substantial risks and uncertainties. All such statements contained in this presentation are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. This law that, in part, gives us the opportunity to share our outlook for the future without fear of litigation if it turns out our predictions were not correct.

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3/15/2024

Investment Thesis

Oral therapeutic candidate targeting \$4.7 billion growth-disorder market

Attractive Market Opportunity	<ul style="list-style-type: none">Global growth hormone (GH) market of ~\$4.7 billion is primed for conversion to oral therapyLead indication, PGHD, is ~\$1.5 billion global opportunity*Market research supports rapid conversion to oral and potential expansion opportunities**	
Novel Asset with Unique MOA	<ul style="list-style-type: none">Oral LUM-201 novel MOA takes advantage of natural physiologyOrphan Drug Designation in US/EU and issued patents in major marketsIP protection through 2042 in the US for novel formulation	
Clear Proof of Concept in PGHD	<ul style="list-style-type: none">PEM strategy de-risks patient selection, identifying likely LUM-201 responders***Phase 2 trials met all primary and secondary endpointsPhase 2 data demonstrated LUM-201 produces significant increase in AHV vs baselineConsistent PK/PD and attractive safety profile to date in > 1,300 subjects studied	
Regulatory Path Clarity	<ul style="list-style-type: none">Positive End-of-Phase 2 meeting with FDA held early Q2 2024 regarding Phase 3 programInitiation of Phase 3 trial anticipated Q4 2024	

Potential for **1st oral therapeutic** to disrupt injectable market for GHD

* Based on gross sales of rhGH worldwide

** Initial Primary Research of PGHD Market conducted for Lumos by Triangle Insights

3 *** PEM (Predictive Enrichment Marker) investigational strategy consists of screening for PEM-positive PGHD patients = Baseline IGF-1 > 30 ng/ml & Peak stimulation GH ≥ 5 ng/ml from single oral dose of LUM-201

Management – Significant Clinical Development and Commercial Experience



Richard Hawkins
Chairman & CEO

Developed Growth Hormone (GH) Receptor Antagonist for Acromegaly at Sensus (sold to Pfizer). Built one of the first contract recombinant protein manufacturing facilities (Covance Biotechnology). Founder of Pharmaco, a pioneer in the contract research organization sector (merged with PPD).



John McKew, PhD
President & Chief Scientific Officer

Prior VP of Research at aTyr Pharma – led team advancing protein-based therapeutics for rare diseases. Former Scientific Director, NIH - National Center for Advancing Translational Science (NCATS) and Therapeutics for Rare and Neglected Diseases (TRND).



Lori Lawley, CPA
Chief Financial Officer

Former SVP, Finance and Controller at Lumos Pharma. Previously, SVP, Finance and Member of the Office of the CEO of NewLink Genetics. Prior to that, Senior Manager in Assurance Services at Ernst and Young.



Pisit "Duke" Pitukcheewanont, MD
Chief Medical Officer

Pediatric endocrinologist and Professor, Clinical Pediatrics, Keck School of Medicine, USC. President, Human Growth Foundation. Former VP Medical Affairs and VP Global Medical Ambassador & Medical Education at Ascendis Pharma; project: long-acting TransCon GH. Former Advisory Board member at Pfizer, Ipsen, Alexion, Ultragenyx, Pharmacia, Serono, others.

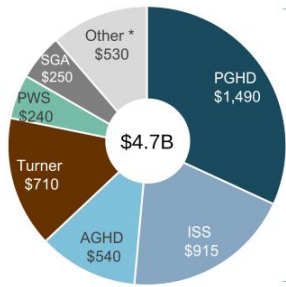


Aaron Schuchart, MBA
Chief Business Officer

Former Chief Business Officer of Aeglea BioTherapeutics. Former leadership roles in Business Development, Strategy, and Finance at Coherus Biosciences, Novartis Diagnostics/Grifols, and Amgen.

Market Opportunity for Oral LUM-201

~\$4.7B 2022 Market by Indication
(Gross, including China, US\$ MM)



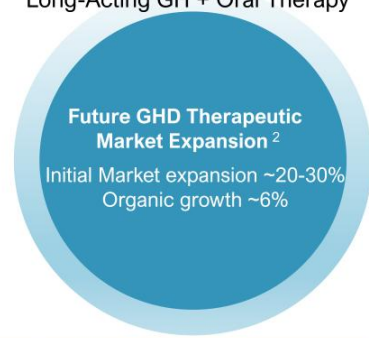
GH Market Growth



Daily rhGH Injections

- Low compliance
- Early discontinuation
- Low referral for moderate PGHD

Expanded Market Opportunity
Long-Acting GH + Oral Therapy



Interview Question:
If a daily oral secretagogue and a weekly rhGH injectable product were both FDA-approved and available for use, which product would you prefer?¹

Physicians

Caregivers

¹ Initial Primary Research of PGHD Market conducted for Lumos by Triangle Insights. Physicians N = 20. Caregivers N = 9.
² Includes ~\$350M in China sales, indication undisclosed, and ~\$65M in Japan sales. Other or Undetermined; also includes global sales for other short stature syndromes such as Noonan Syndrome, SHOX deficiency, cancer cachexia, etc.
Source: Internal Lumos GH Market Assessment, based on: EvaluatePharma consensus estimates, GlobalData, "GHD Forecast", 2021/04; Grand View Research, "rhGH Market Analysis and Segment Forecast" - updated 2022 Q1; IQVIA/MIDAS, Japan Pricing Research (Satoru GK, 2023); Regional market participant interviews; Lumos/Akrolyth Analysis

LUM-201 Program Pipeline

	Study	Pre-Clinical	Phase 1	Phase 2	Phase 3	Status
LUM-201 (Ibutamoren) in Moderate PGHD	Dose-finding trial	OraGrowthH210 TRIAL				Phase 2 Topline Data met endpoints (Nov 2023) Positive End-of-Phase 2 meeting with FDA
	Long-term extension	OraGrowthH211 TRIAL				Long-term extension study for OraGrowth Trials: Ongoing enrollment of patients from Phase 2 trials
	PK/PD trial	OraGrowthH212 TRIAL				Phase 2 Topline Data met endpoints (Nov 2023) Data confirms LUM-201's pulsatile MOA
	Switch trial	OraGrowthH213 TRIAL				Switch trial evaluating LUM-201 in subjects from rhGH arm of OraGrowthH210 Trial: Ongoing
LUM-201 in NAFLD	Phase 2 pilot trial	MGH pilot trial				Pilot trial initiated by Mass Gen Hospital (MGH) evaluating LUM-201 in NAFLD: Enrolling

Lumos Pharma is evaluating PWS, ISS, other indications for Phase 2 studies with LUM-201

PGHD Pediatric Growth Hormone Deficiency NAFLD Non-Alcoholic Fatty Liver Disease PWS = Prader-Willi Syndrome ISS = Idiopathic Short Stature
 MGH Trial supported by prior data evaluating rhGH in NAFLD: (ENDO 2022) JES, Volume 6, Issue Supplement_1, November-December 2022, Page A525, and JES, June 2023.

FDA End-of-Phase 2 Meeting Update



Positive, constructive meeting with ~30 FDA staff in attendance



Acknowledged that we are not a GH product – but a novel growth promotor



Tone was collaborative and focused on approaches for a Phase 3 pivotal trial



FDA suggested that a placebo-controlled Phase 3 trial design is an appropriate option for a GH secretagogue like LUM-201, subject to FDA review

LUM-201 Augments Endogenous Pulsatile Release of Growth Hormone

Single Daily Bolus Injection
of Exogenous rhGH

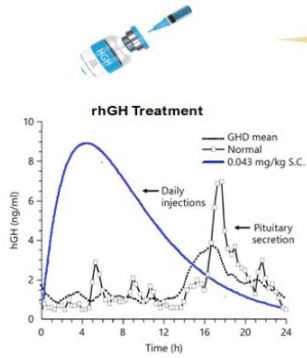


Figure 1

Single Daily Dose of LUM-201
(3.2 mg/kg/day)

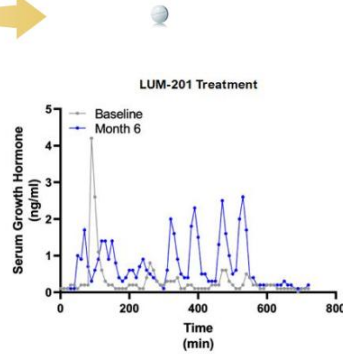


Figure 2

LUM-201 Value Proposition

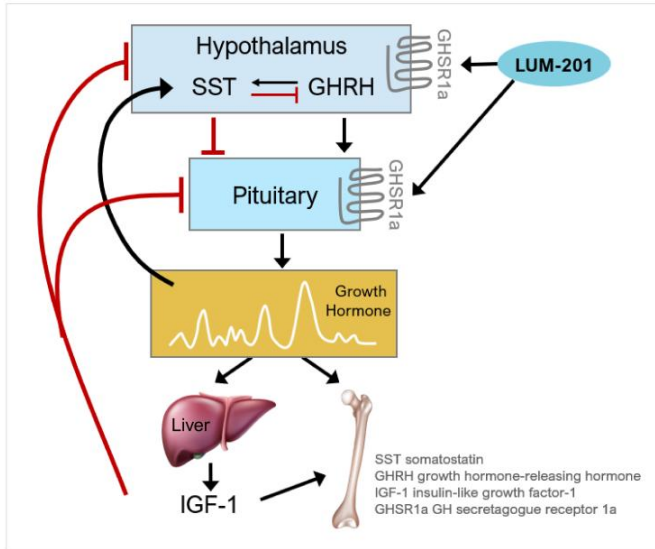
- Daily oral therapy
- Normalizes GH and IGF-1 levels through increase in endogenous pulsatile release of Growth Hormone levels
- Consistent PD effect over 24 hours*
- MOA avoids risk of IGF-1 excursions
- Favorable investigational safety profile with >1,300 patients treated to date

Figure 1: Advanced Therapies in Pediatric Endocrinology and Diabetology. Endocr Dev. Basel, Karger, 2016

Figure 2: Cassoria, F, et al. IMPE, March 2023; GH concentrations sampled every 10 minutes for 12-hour period at baseline and after six months of daily oral treatment

* Merck 020 study

LUM-201 Restores Natural Growth Hormone & IGF-1 Secretion

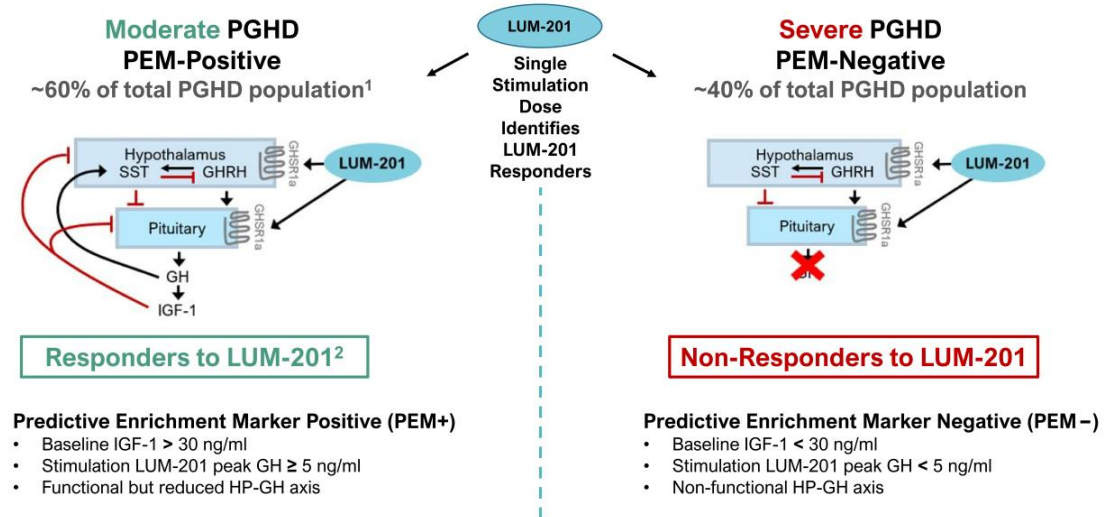


**LUM-201 mimics natural release of growth hormone (GH)
Different from injections of synthetic GH**

- LUM-201 is an oral GH secretagogue*
- Acts on specific receptors in hypothalamus and pituitary to stimulate release of GH¹
- Increases the amplitude of natural pulsatile GH secretion, ^{2,3} normalizing GH levels after 6 months on therapy⁴
- LUM-201 stimulated GH release regulated by natural GH/IGF-1 feedback mechanisms
- Differentiated mechanism versus exogenous injection of recombinant human growth hormone (rhGH) products

¹ Howard 1996 Science ² Nass 2008 Ann Intern Med ³ Chapman 1997 J Clin Endocrinol Metab ⁴ Supported by Lumos Pharma Topline Phase 2 Data
⁹ * GH secretagogue = molecule that stimulates the secretion of growth hormone (GH)

PEMs Enrich Trials for Patients Likely to Respond to LUM-201*



* PEM (Predictive Enrichment Marker) investigational strategy consists of screening for PEM-positive PGHD patients = Baseline IGF-1 > 30 ng/ml & Peak stimulation GH ≥ 5 ng/ml from single oral dose of LUM-201
 1 Blum 2021 JES 2 Bright 2021 JES
 HP-GH axis – hypothalamic pituitary growth hormone axis

Phase 3 Trial Design Options Discussed with the FDA

Lumos Submitted Non-Inferiority Study

- LUM-201 vs rhGH control
- 12-month duration
- Non-inferiority margin
 - The lower bound of non-inferiority margin must be above the clinically meaningful AHV growth rate

Placebo-Controlled Study

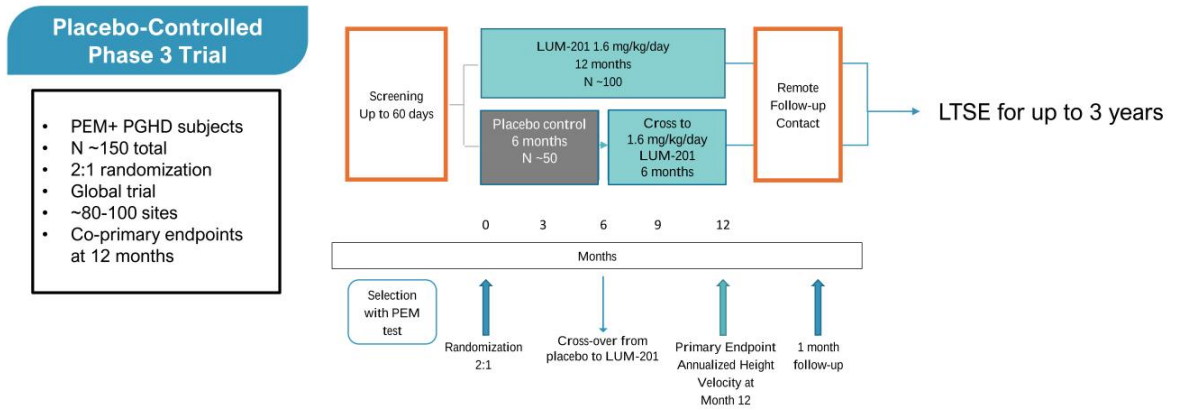
- LUM-201 vs placebo
- 12-month duration
 - Must show clinically meaningful growth rate above the placebo growth rate
 - Potential benefit for placebo arm is an important design consideration
- This presumably arose from their recognition of our **unique** mechanism of action compared to GH

FDA suggested that a placebo-controlled Phase 3 trial is an appropriate option for a GH secretagogue such as LUM-201

- 12-month double-blind placebo-controlled trial in PEM+ PGHD patients
 - All placebo subjects cross over to LUM-201 at 6 months
- ~150 subjects in global study across ~80-100 sites
 - 2:1 randomization – 1.6 mg/kg/day LUM-201:Placebo
- Co-primary endpoints at 12 months:
 - LUM-201 arm at 12 months – lower bound of the 95%CI > 6.7 cm/yr AHV
 - Placebo crossover arm – pairwise comparison within-subject of LUM-201 AHV at 6-months vs. Placebo AHV at 6-months
 - LUM-201 at 6 months – lower bound of the 95%CI > 6.7 cm/yr AHV

We believe a placebo-controlled Phase 3 trial increases the probability of success

12-month, 2:1 randomization, double-blind, single arm cross-over design with all placebo patients switched to LUM-201 at 6 months, who then continue for an additional 6 months on treatment



Key Milestones Support Path for Oral LUM-201 to Disrupt Injectable GH Market

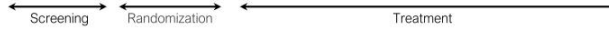
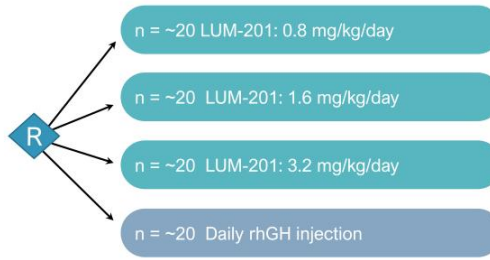
- Positive End-of-Phase 2 meeting with FDA supportive of registrational path forward
 - FDA recognized LUM-201, a growth hormone secretagogue, as a novel growth promoter
 - FDA acknowledged the use of a placebo-controlled clinical trial design as an appropriate option for a LUM-201 Phase 3 trial
- Phase 3 initiation expected by year-end 2024
 - Proposal of placebo-controlled design should reduce regulatory risk and improve likelihood of success

OraGrowthH210 Trial: Phase 2 Trial in Naïve Moderate PGHD

OraGrowthH210 TRIAL

- n = 82
- PEM(+) PGHD subjects
- Inclusion: stim GH \geq 5 ng/ml and baseline IGF-1 $>$ 30 ng/ml
- rhGH treatment naïve
- ~45 trial sites US & International

Primary Outcome Data (n = 82) – at 6 months on therapy
Total Study Duration – 24 months



Objectives

Study Objectives:

- Prospectively confirm utility of PEM strategy
- Evaluate reproducibility of PEM classification
- Annualized Height Velocity (AHV)

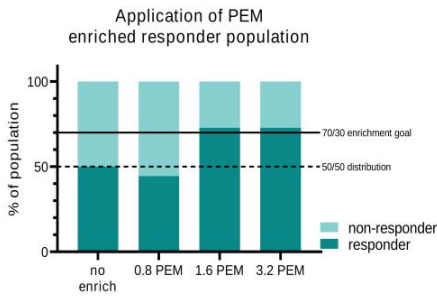
Goals:

- Determine optimal dose for Phase 3

Study not powered to show statistical non-inferiority

OraGrowthH210 Met Primary & Secondary Statistical Objectives:
 PEM Test Enriches the Responder Population & Yields Highly Reproducible Results

Highlights



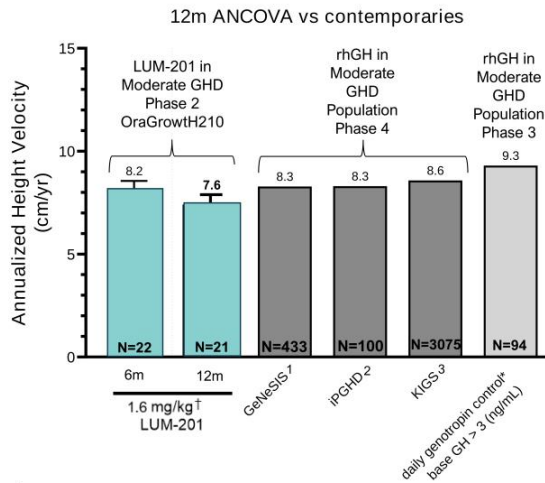
PEM Test Reproducibility	
Subjects with Positive Agreement on PEM Tests	76/76
Reproducibility Rate	100%
95% Confidence Interval	(95.3%, 100%)

- PEM test ensures patients enrolled in the study are capable of secreting GH in response to a single-dose of LUM-201
- PEM test is highly reproducible
- PEM-positive criteria:
 - PGHD patients with baseline IGF-1 > 30 ng/ml
 - Peak stimulated GH \geq 5 ng/ml after a single 0.8 mg/kg dose of LUM-201

Enrichment strategy demonstrated that >70% of PEM+ subjects met pre-specified target growth in 1.6 and 3.2 mg/kg/day cohorts

PEM positive classification was 100% reproducible and exceeded pre-specified statistical objective

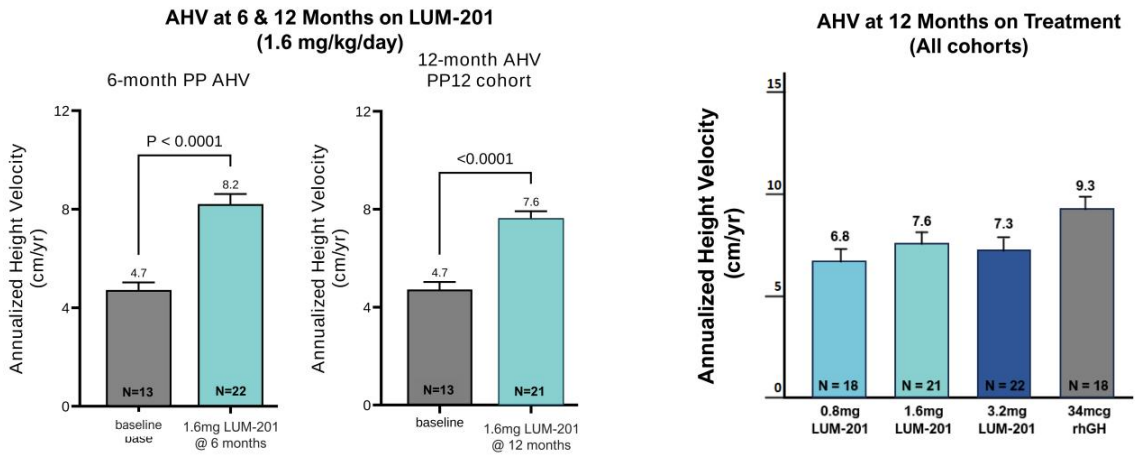
OraGrowthH210: LUM-201 Growth Comparable to Multiple 12-Month Historical Datasets



Highlights

- AHVs range from 8.3-9.3 cm/yr in historical datasets of moderate PGHD patients treated with daily rhGH
- LUM-201 AHVs of 8.2 and 7.6 cm/yr at 6 and 12 months, respectively, were in line with these historical rhGH growth rates in similar moderate patient populations

[†] ANCOVA values represent an analysis of covariates incorporating multiple baseline demographic terms. LUM-201 at 6m PP and 12m PP. Twelve-month LUM-201 AHV updated to include preliminary analysis of full 12-month dataset. Bars represent Least Squares Mean (LSM); Error bars represent the Standard Error of LSM
 Sources: ¹ Blum et al JES 2021, ² Lechuga-Sancho et al JPEM 2009, ³ Ranke et al JCEM 2010
^{*} Daily Genotropin control group for Somatrogon Ph3 dosed at 0.034 mg/kg/day (equates to 0.24 mg/kg/wk); subjects were stratified based on GH production during a standard stim test. JCEM Volume 107, Issue 7, July 2022. Pages e2717–e2728.

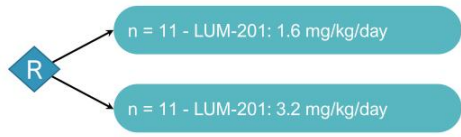


Significant increase in growth on 1.6 mg/kg/day LUM-201 vs baseline suggests this optimal LUM-201 dose is likely to demonstrate superior growth to placebo in Phase 3 trial

OraGrowthH212 TRIAL

- n = 22
- Open-label study
- Moderate PGHD patients
- rhGH-treatment naïve
- Dosing to near-adult height
- Single, specialized clinical site in Santiago, Chile
- Q10 minute GH sampling for 12 hours

Primary Outcome Data (n = 22) – at 6 months on therapy
 Total Study Duration – Subjects on therapy to near adult height



Objectives

Study Endpoints:

- Assess LUM-201 effect on endogenous GH pulsatility and Annualized Height Velocity (AHV)
- Evaluate PK/PD in children

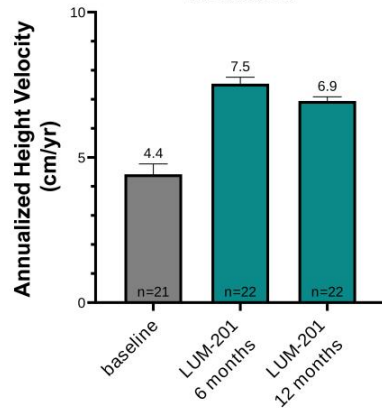
Goals:

- Confirm prior PK/PD data in adults & subset of Merck 020 trial
- Support future regulatory filings & commercialization

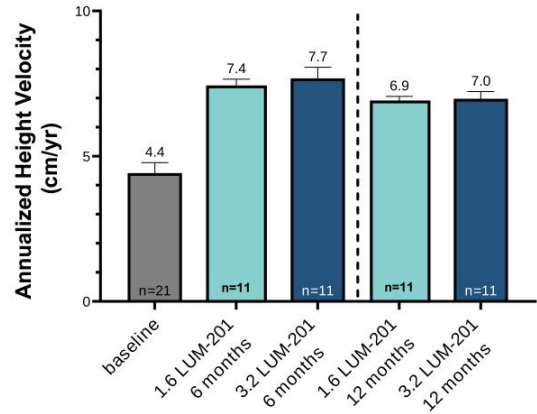
OraGrowthH212 was a single-site trial with a more homogenous patient population than larger international OraGrowthH210 Trial

Full OraGrowthH212 Data at 12 Months Demonstrate Meaningful Growth from Baseline and Durable Effect to 1 year on Treatment

**AHV at 6 & 12 Months on Treatment
(Combined 1.6 & 3.2 mg/kg/day LUM-201)
vs Baseline**

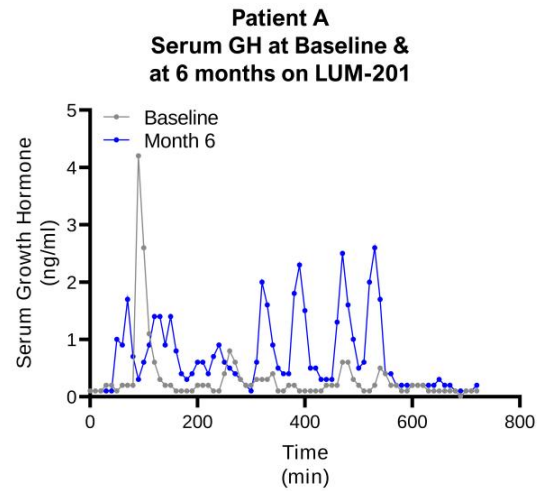


**AHV at 12 Months on Treatment
vs Baseline**



OraGrowthH212: LUM-201 Augments GH Pulses, Increases IGF-1 and Growth Rate **lumos**
 Month 6 for Patient A (3.2 mg/kg/day)

		Baseline	6 months LUM-201 3.2 mg/kg/d
IGF-1 (ng/ml)		48	111
		% change from baseline*	131%
Q10m 12h GH	AUC ₀₋₁₂ (ng*hr/ml)	252.9	481.8
		% change from baseline*	91%
Height velocity (cm/yr)		4.4	9.4

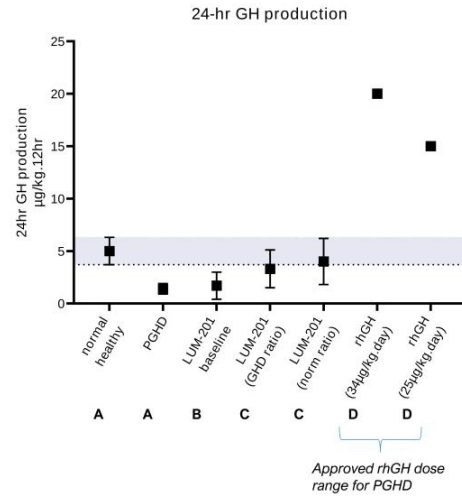


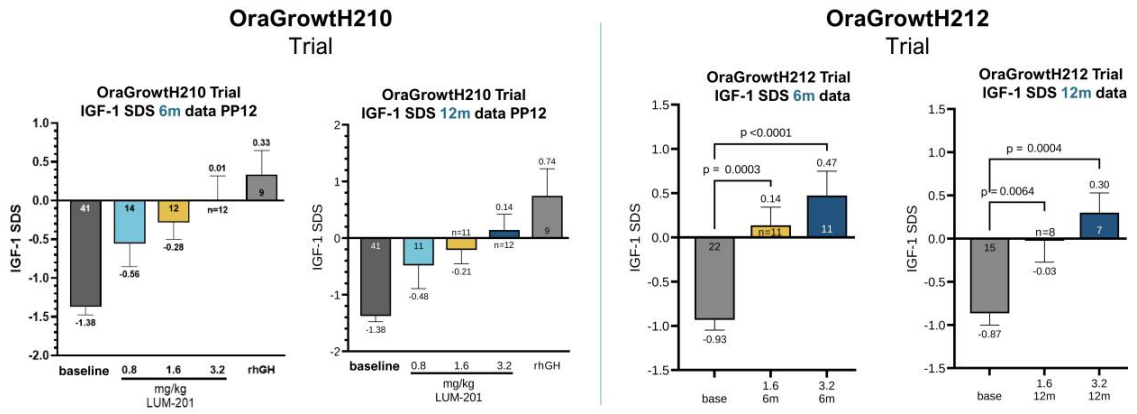
LUM-201 raises AHV from baseline by augmenting pulsatile secretion of GH and increasing IGF-1

By Increasing Endogenous 24-hour Pulsatile GH Secretion, LUM-201 Achieved Similar Growth to Exogenous Injectable rhGH, with Only ~20% of GH Concentration Levels

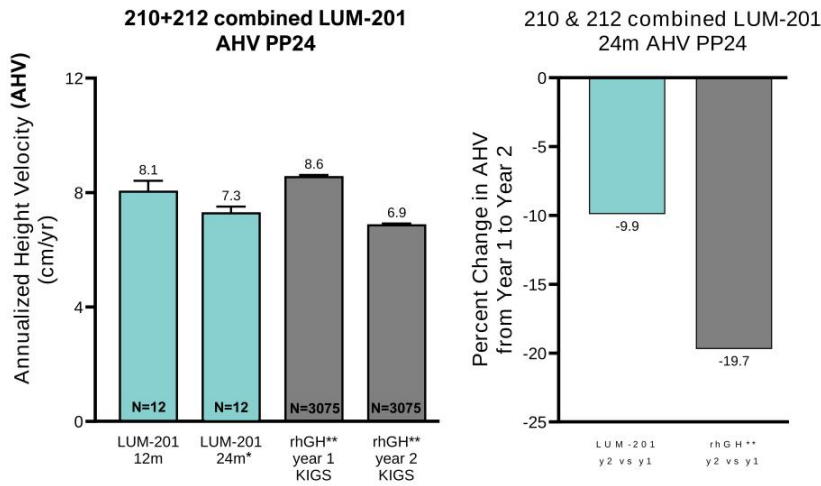
- LUM-201 increased GH to levels similar to a normal growing child
- LUM-201 induced the release of ~20% of the GH from a 34 mcg/kg/day rhGH daily injection, equating to ~26% of GH compared to a 25 mcg/kg/day rhGH dose
- Restoring pulsatility and 24-hr PD effect makes LUM-201 growth more GH efficient as it still captures majority of the growth on rhGH

Data Sources/Calculations:
 A – Zadik et al Horm Res 1992, 24 hour concentrations calculated based on 12 hour measurement
 B – Combined 1.6 and 3.2 mg/kg/day cohorts in '210 and '212 studies
 C – 24-hour calculation from 12-hour data using both GHD factor and normal healthy factor
 D – Adapted from data in Albertsson-Wikland et al JCEM 1994; 24-hour exposures listed reflect absorbance/bioavailability of ~60% of the administered dose





- LUM-201 normalizes IGF-1 within 6 months with durable effect to 12 months
- No subjects > 2 Standard Deviation Score (SDS) between 0 and 12 months



Highlights

- Preliminary data demonstrated LUM-201 AHV durable to 24 months
- More moderate year 2 AHV decline than rhGH likely due to LUM-201 restoration of GH and IGF-1 to normal levels via pulsatile secretion

AHV values from the OraGrowth studies are based on ANCOVA model (details provided on previous slides)

* At 24 months, data include a subset of subjects from OraGrowthH210 trial who met protocol criteria to continue past 12 months.

** Ranke et.al, 2010 – Pfizer KIGS database rhGH treated cohort of moderate prepubertal GHD children; mean AHV for the moderate GHD cohorts were 8.58 cm/yr in year 1 and 6.89 cm/yr in year 2.

Favorable
Investigational
Safety
Profile

- No meaningful treatment-related Serious Adverse Events (SAEs)
- No drop-outs due to SAEs or AEs
- No meaningful safety signals observed in laboratory values, adverse events data, or in EKG values to date
- Treatment related AEs in 1.6 and 3.2 groups:
 - Increased appetite (23), Pain in extremity (7), Arthralgia (5)

OraGrowthH210 and OraGrowthH212 Phase 2 Topline Data¹

- Topline Phase 2 data met all primary and secondary endpoints
- PEM test was reproducible and predicted response to LUM-201
- Oral LUM-201 significantly increased growth rates from baseline
- LUM-201 restored normal GH secretion and IGF-1 levels through increased amplitude of GH pulsatility
- LUM-201 promoted growth similar to injectable rhGH with only 20% of GH concentration levels
- Preliminary 24-month data demonstrated sustained growth on LUM-201
- Favorable investigational safety profile to date

Updated OraGrowthH210 and OraGrowthH212 Data²

- Updated OraGrowthH data corroborate prior data showing durable LUM-201 treatment effect
 - Significant increase in growth from baseline at 6 and 12 months on LUM-201
 - LUM-201 continues to demonstrate durability of response to 12 and 24 months

¹ Topline data as announced November 2023.

²⁶ ² Updated data include full 12-month AHV data for OraGrowthH210 and OraGrowthH212 trials plus additional combined 24-month AHV data announced Q2 2024.

Potential Advantages of Oral LUM-201 Over Current Injectable rhGH

- Oral therapy preferred over injections for pediatric GHD and should expand the market^{1,2}
- LUM-201 growth rates more stable vs rhGH over time^{3,4,5}
 - Daily rhGH growth rate declines ~20% from year 1 to year 2 in moderate PGHD population^{4,5}
 - Year 1 to year 2 growth decline in LUM-201 treated subjects was 10% in similar population^{4,5}
- Restores natural pulsatile GH release without IGF-1 excursions^{3,4}
- Normalizes growth rates at ~20% of GH exposure of injectable rhGH^{4,5}
- Cost of goods less than injectable rhGH

Additional Indications for Oral LUM-201

- PWS & ISS: LUM-201 has potential to treat up to 11 indications currently treated with injectable rhGH
- NAFLD: LUM-201 has potential to reduce liver fat similar to historical data with injectable GH
- Obesity: LUM-201 + GLP1 combo has potential to improve muscle mass retention during weight loss

¹ Initial Primary Research of PGHD Market conducted for Lumos by Triangle Insights showed majority of physicians and caregivers preferred daily oral to weekly injections. Physicians N = 20. Caregivers N = 9. ² Primary market research performed by Blue Matter Consulting, internal Lumos analysis based on KOL interviews and publications
³ Dauber et.al. PES 2024. ⁴ Clayton, et.al. 2024. ⁵ Clayton GRS 2024.

LUM-201: Exclusivity and Barriers with Orphan Designation and IP

Novel Formulation Patent	<ul style="list-style-type: none"> • Patent allowance granted March 14, 2024, by USPTO for novel LUM-201 formulation • Formulation enables capsule with mini-tablets of LUM-201 drug product inside • Extends intellectual property protection through 2042 for covered formulations
Orphan Drug Designation	<ul style="list-style-type: none"> • Orphan Drug Designation (ODD) granted in US & EU for GHD in 2017 • LUM-201 eligible for 12 years of exclusivity in EU and 7.5 years of exclusivity in US*
Intellectual Property	<ul style="list-style-type: none"> • Prior patent granted for “Detecting & Treating GHD” • Use of LUM-201 in PGHD and other GHD indications based on PEM strategy • Patents for LUM-201 in GHD with protection through 2036 • Patents granted in US, Australia, EU, Israel, Japan, S. Korea, Hong Kong and Ukraine • Additional applications pending in multiple jurisdictions • Applications for LUM-201 in NAFLD being prosecuted in multiple jurisdictions





Cash, Equivalents & Short-term Investments	\$23.2M
Debt	\$0
Shares Outstanding	8.1M
Cash Runway	Through 3Q 2024
Fiscal Year End	December 31



Cash, cash equivalents, & short-term investments to support operations through 3Q 2024, inclusive of activities related to advancing the PGHD program into Phase 3

Investment Thesis

Oral therapeutic candidate targeting \$4.7 billion growth-disorder market

Attractive Market Opportunity	<ul style="list-style-type: none">Global growth hormone (GH) market of ~\$4.7 billion is primed for conversion to oral therapyLead indication, PGHD, is ~\$1.5 billion global opportunity*Market research supports rapid conversion to oral and potential expansion opportunities**	
Novel Asset with Unique MOA	<ul style="list-style-type: none">Oral LUM-201 novel MOA takes advantage of natural physiologyOrphan Drug Designation in US/EU and issued patents in major marketsIP protection through 2042 in the US for novel formulation	
Clear Proof of Concept in PGHD	<ul style="list-style-type: none">PEM strategy de-risks patient selection, identifying likely LUM-201 responders***Phase 2 trials met all primary and secondary endpointsPhase 2 data demonstrated LUM-201 produces significant increase in AHV vs baselineConsistent PK/PD and attractive safety profile to date in > 1,300 subjects studied	
Regulatory Path Clarity	<ul style="list-style-type: none">Positive End-of-Phase 2 meeting with FDA held early Q2 2024 regarding Phase 3 programInitiation of Phase 3 trial anticipated Q4 2024	

Potential for **1st oral therapeutic** to disrupt injectable market for GHD

* Based on gross sales of rhGH worldwide

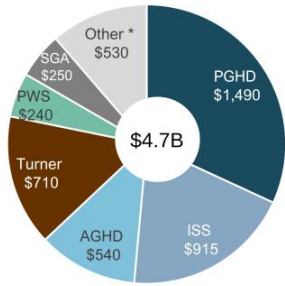
** Initial Primary Research of PGHD Market conducted for Lumos by Triangle Insights

30 *** PEM (Predictive Enrichment Marker) investigational strategy consists of screening for PEM-positive PGHD patients = Baseline IGF-1 > 30 ng/ml & Peak stimulation GH ≥ 5 ng/ml from single oral dose of LUM-201

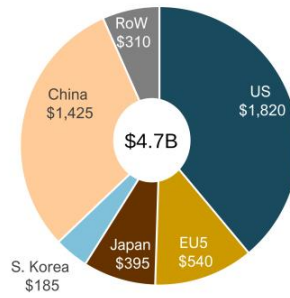
Supplementary Materials

rhGH Market Gross Sales – by Indication and by Region

2022 rhGH Global Sales by Indication
(Gross, Including China, US\$ MM)



2022 rhGH Global Sales by Region
(Gross, US\$ MM)



Key growth drivers for rhGH market suggest promising outlook



- Long-acting rhGH products addressing limitations of daily rhGH treatment burden
- Growing awareness about GH-related diseases
- Increasing healthcare access and spend in developing regions



- Very mature market
- Pricing pressures
- Inconsistent reimbursement policies

*Includes ~\$350M in China sales, indication undisclosed, and ~\$65M in Japan sales, Other or Undetermined; also includes global sales for other short stature syndromes such as Noonan Syndrome, SHOX deficiency, cancer cachexia, etc.

Source: Internal Lumos GH Market Assessment, based on: EvaluatePharma consensus estimates, GlobalData, "GHD Forecast", 2021/04; Grand View Research, "hGH Market Analysis and Segment Forecast", updated 2022 Q1; IQVIA/MIDAS; Japan Pricing Research (Satoru GK, 2023); Regional market participant interviews; Lumos/Akrolyth Analysis

LUM-201 History



Developed LUM-201 to improve health span

>1,200 subjects studied, primarily elderly adults

- ✓ GH Levels ↑
- ✓ IGF levels ↑
- ✓ Consistent improvements in body composition¹
- ✓ Sustained Effect to 24 months¹
- Discontinued for strategic reasons



Performed post hoc analysis of PGHD study and developed clinical enrichment strategy²

104 PGHD subjects treated in two Phase 2 studies:

- ✓ OraGrowthH210 – PEM* strategy validation and dose selection for Phase 3, n = 82
- ✓ OraGrowth212 – PK/PD demonstrating pulsatility MOA differentiation, n = 22
- ✓ Encouraging investigational safety profile at doses almost 4X higher than dose previously used in adult studies
- ✓ New patent estate around PEM strategy, formulation, and methods of treatment
- Phase 3 registrational study in PEM+ PGHD subjects planned for Q4 2024

**Predictive Enrichment Marker*

¹ Nasa 2008 Ann Intern Med
² Performed by Lumos licensor, Ammonett Pharma

LUM-201 Potential in Obesity and Cardiometabolic Indications GLP1-Ra/LUM-201 Combination to Improve Quality of Weight Loss

Obesity is a growth hormone (GH) deficient state

- GH secretion is blunted in obesity
- Growth hormone deficient adults have similar metabolic and body composition consequences as normal obese subjects
- Increases in GH and/or IGF-1 inhibits myostatin, leading to increases in muscle mass²

Emerging unmet medical needs arising from incretin therapy in obesity

- Disproportionate loss of lean mass loss with negative clinical outcomes
- Post treatment rebound¹
- Next generation oral therapies in development

Restoring normal physiology with a GH secretagogue in combination with a GLP-1 agonist should provide high quality of weight loss

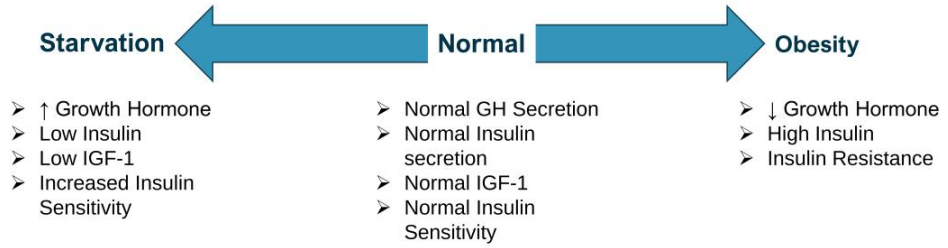
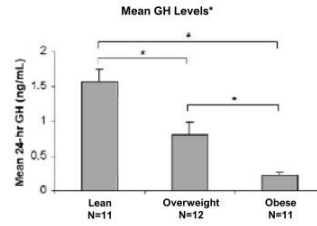
- Increase in pulsatile release of GH by augmenting natural physiology
- rhGH therapy repartitions visceral fat to the periphery and increases muscle mass
- Obtain weight loss benefits from GLP-1 with body composition and metabolic benefits of GH therapy in a physiologically controlled manner

¹Wilding, JPH, et al. New England Journal of Medicine, 2021
²Liu et al. J Clin Endocrinol Metab 2003, 88(11):5490-5496

Endogenous GH Secretion is Blunted in Obesity¹

Endogenous GH levels are reduced in a stepwise manner with disease severity . . .

. . . This finding has been consistent across all obese populations²

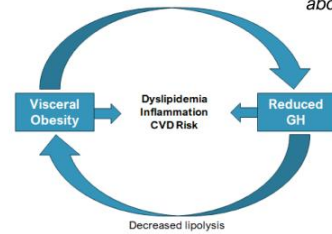


¹Utz, et al, "Androgens May Mediate a Relative Preservation of IGF-I Levels in Overweight and Obese Women Despite Reduced Growth Hormone Secretion, J Clin Endocrinol Metab, October 2008
²Dichtel, et al, "Growth Hormone and Insulin-like Growth Factor 1 Regulation of Nonalcoholic Fatty Liver Disease", J Clin Endocrin Metab, 2022

Beyond its effects on bone growth and musculoskeletal anabolism, GH plays an important role in the regulation of lipid metabolism, body fat distribution, inflammation and vascular health¹

Untreated Adult Growth Hormone Deficiency (AGHD) and Obesity share many common features:

- Visceral fat accumulation in the abdomen
- Blunted GH secretion
- Insulin resistance
- Higher inflammatory markers
- Increased cardiovascular mortality
- Higher incidence of NAFLD²



Self-reinforcing cycle of increased visceral fat and reduced GH in states of abdominal obesity¹

GH increases IGF-1 Production: Growth of Skeletal Muscle is Modulated by the Combined Actions of IGF-1 and Myostatin

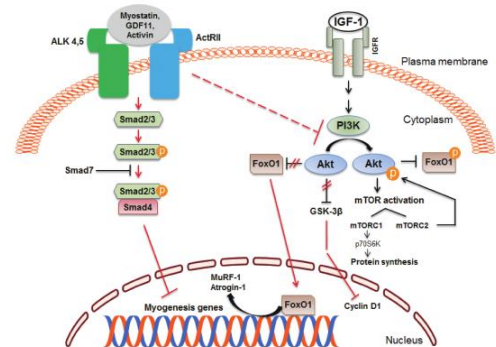
- IGF-1 and myostatin have contrasting roles in regulating skeletal muscle size and growth and act on opposing signaling pathways¹

Myostatin Targeting:

- Myostatin's target, ActRII, is broadly expressed and activated by a variety of endogenous ligands
- Non-specific myostatin pathway inhibitors have exhibited safety concerns in the clinic and in animal models²

LUM-201:

- MOA increases endogenous GH pulsatility, leading to increased muscle mass³
 - Selective targeting of myostatin inhibition
 - Anabolic action of GH

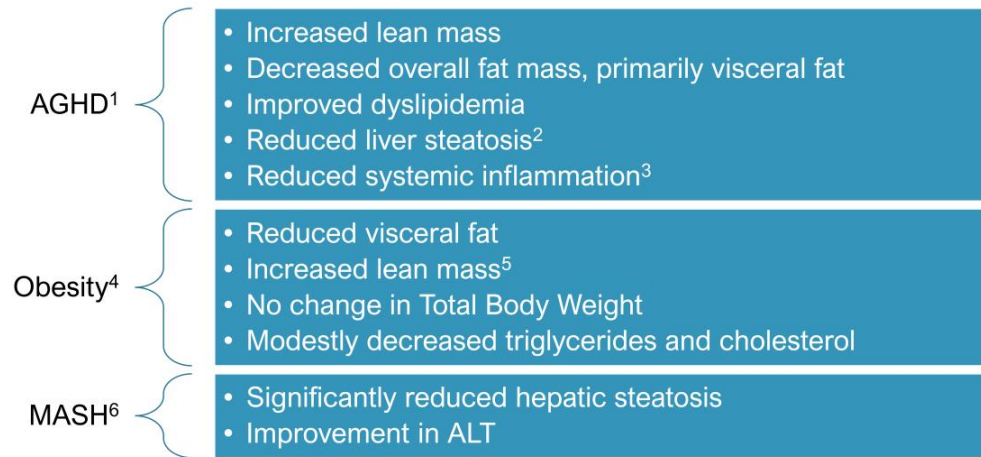


¹Ahima and Park Endocrinol Metab 2015, 30:235-245

²Suh et al, PNAS 2020, 117(9):4910-4920

³Nass 2008 Ann Intern Med

GH Treatment Effects on Adult Growth Hormone Deficiency (AGHD), Obesity, and MASH



¹Stanley, Grinspoon, "Effects of growth hormone-releasing hormone on visceral fat, metabolic, and cardiovascular indices in human studies", Growth Hormone & IGF Research 25 (2015) 59-65

²Growth hormone reverses nonalcoholic steatohepatitis in a patient with adult growth hormone deficiency, Takahashi, et al, Gastro, 2007

³Bredella MA, et. al, Eur J Endocrinol. 2012;166(4):601-611

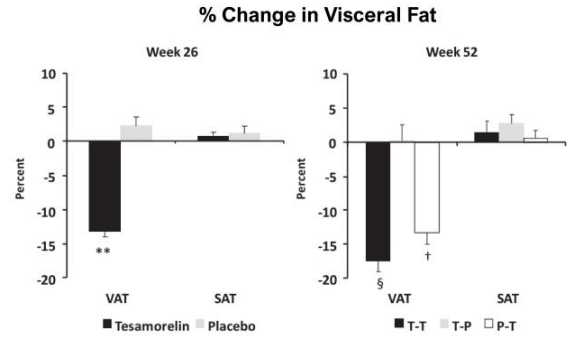
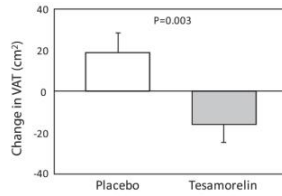
⁴Johannsson, et al, "Growth Hormone Treatment of Abdominally Obese Men Reduces Abdominal Fat Mass, Improves Glucose and Lipoprotein Metabolism, and Reduces Diastolic Blood Pressure", Journal of Clinical Endocrinology and Metabolism, 1997

⁵W.A. Bredella, A.V. Gerweck, E. Lin, M.G. Landa, M. Torriani, D.A. Schoenfeld, et al., Effects of GH on body composition and cardiovascular risk markers in young men with abdominal obesity, J. Clin. Endocrinol. Metab. 98 (9) (2013) 3864-3872.

⁶Ditchel, LE, et. al, J. Clin Endocrinol Metab. 2023, 108, e1542-e1550, MASH = Metabolic Dysfunction-Associated Steatohepatitis (formerly NASH, Non-alcoholic steatohepatitis)

Strong Evidence with an Injectable GHRH Analog¹

- Tesamorelin (analog of GHRH) is an injectable peptide that stimulates GH Release
 - Different biological mechanism than LUM-201
 - Approved to treat HIV Lipodystrophy
- 52-week study in 60 abdominally obese subjects (Standard GH stim test ≤ 9 ug/L)
 - ✓ Significant decrease in visceral fat (-1.7 kg)
 - ✓ Significant increase in lean mass (+1.4 kg)
 - ✓ No change in BMI
 - ✓ Significant decrease in triglycerides (-37 mg/dL)
 - ✓ Carotid IMT decreased (-0.04 mm)
 - ✓ No change in glucose

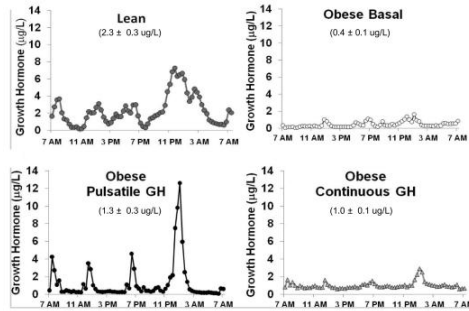


Pulsatile Delivery of GH Almost Doubles the Rate of Lipolysis in Obese Subjects vs. Continuous Infusion of GH¹

Study Objective: Mimic normal GH physiology to determine treatment effects in obese subjects

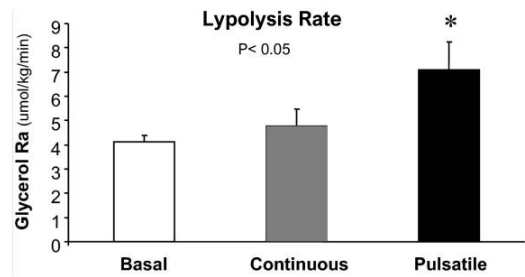
Study Design

- 9 Obese subjects were dosed rhGH 0.015 mg/kg/day for three days, switched as follows:
 - Continuous infusion
 - 4 pulses mimicking normal peak cycles



Results:

- Mean 24-GH plasma concentrations similar
- IGF-1 concentrations in plasma higher in Continuous treatment arm
- Glycerol Rate of Appearance in plasma (Ra), an index of whole-body lipolytic rate nearly doubled in GH pulsatile GH arm
- Glucose levels similar in all groups



Highlights from LUM-201 Adult Studies

Setting	Treatment Duration ¹	Increase in Serum IGF-1	P-Value	N ¹	Key Findings
Healthy Elderly	12 months	50%	<0.001	43	LUM-201 restored and maintained GH and IGF-1 concentrations back to lower limit of normal for young adults and improved fat free mass ¹ ; Functional improvements in knee and shoulder strength tests vs placebo ²
	24 months	54%	<0.001	17	
Obesity study	8 weeks	~36%	<0.001	12	Significant increase in fat free mass; longer studies encouraged ³
Caloric restriction	7 of 14 days	~40%	<0.01	8	LUM-201 reverses diet-induced nitrogen wasting ⁴
Postmenopausal osteoporosis	12 months [†]	~40%	<0.05	204	Increase in biomarkers of bone formation and resorption, increased bone mineral density (BMD) at the femoral neck; no net change in Total Body BMD ⁵

¹Nass et al Ann. Intern Med 2008

²Unpublished data

³Svensson et al J. Clin. Endocrinol. Metab. 1998

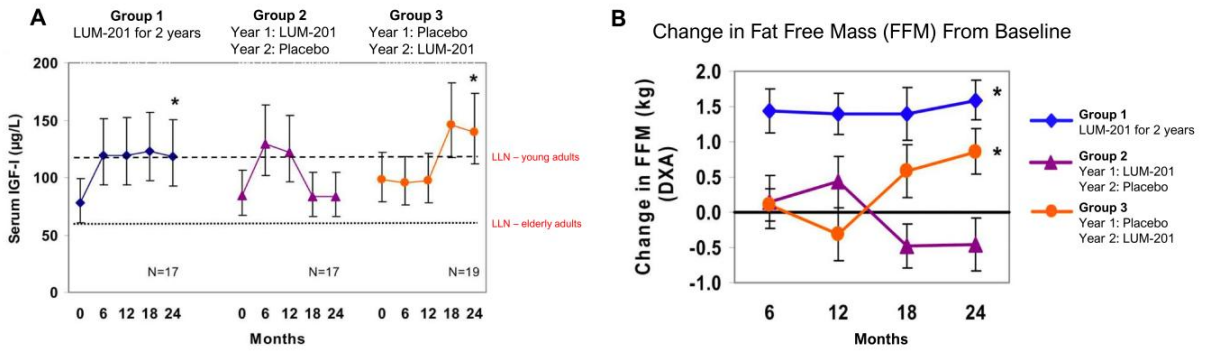
⁴Murphy et al J. Clin. Endocrinol. Metab. 1998

⁵Murphy et al J. Clin. Endocrin. Metab. 2001

[†] IGF-1 data at 12 months treatment, treatment to 18 months

LUM-201 PD and Clinical Effects Are Durable in Healthy Elderly¹

Normalized IGF-1 levels and improved fat free mass from baseline



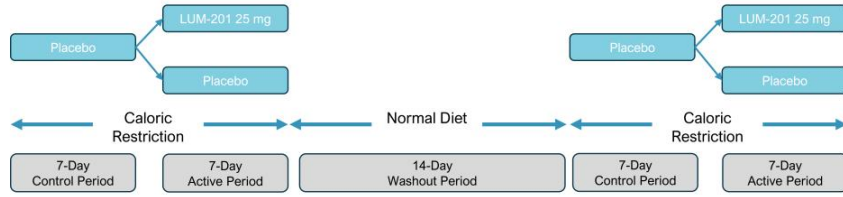
Healthy elderly adults treated with 25mg LUM-201 once daily for up to 24 months

Treatment with LUM-201 restored IGF-1 concentrations to those of normal healthy young adults, increased fat free mass, and demonstrated a sustained effect for up to 24 months

¹Nass 2008 Ann Intern Med (Supplemental Information) Barred data represent 95% Confidence Interval Asterisk indicates significant change from baseline (Bonferroni-adjusted P-value: Panel A P<0.001; Panel B P=0.026) LLN – Lower Limit of Normal DXA – Dual X-ray Absorptiometry

Treatment With LUM-201 Increased Nitrogen Balance In Catabolic State¹

Study Design: Double-blind, placebo-controlled, randomized, two period, crossover study in healthy young adult volunteers



Nitrogen balance AUC, g/day	LUM-201	Placebo
During Active Period	+2.69 +/- 5.0	-8.97 +/- 5.3

LUM-201 significantly² improved nitrogen balance AUC over the 7 days of treatment during the active period.

- Nitrogen balance is a measurement of anabolism (lean body mass)
- Serum GH and IGF1 levels also significantly³ increased with LUM-201 treatment

