

**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**

May 15, 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.

Section 2 - Financial Information

Item 2.02. Results of Operations and Financial Condition.

On May 14, 2024, Lumos Pharma, Inc., a Delaware corporation (the "Company"), issued a press release providing an operational update and reporting results for the first quarter ended March 31, 2024 ("Press Release").

A copy of the Press Release and the First Quarter 2024 Financial Results Presentation are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

The information in this Current Report, including Exhibits 99.1 and 99.2 attached hereto are furnished under Item 2.02 of this report and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated May 14, 2024, entitled " Lumos Pharma Announces Positive End-of-Phase 2 Meeting with FDA and Reports First Quarter 2024 Results "
99.2	First Quarter 2024 Financial Results Presentation

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: May 15, 2024

LUMOS PHARMA, INC.,
a Delaware corporation

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



Lumos Pharma Announces Positive End-of-Phase 2 Meeting with FDA and Reports First Quarter 2024 Financial Results

Outcome from End-of-Phase 2 Meeting Supportive of a Placebo-Controlled Phase 3 Trial

Updated 12 and 24-Month Data from Phase 2 OraGrowthH210 and OraGrowthH212 Trials Continue to Show Oral LUM-201 Achieves Significant Increase in Growth from Baseline, Durable Effect to 24 Months

Company to Host Conference Call May 15, 2024 at 8:30AM ET

AUSTIN, TX, May 14, 2024 (GLOBE NEWSWIRE) – [Lumos Pharma, Inc.](#) (NASDAQ:LUMO), a clinical stage biopharmaceutical company focused on therapeutics for rare diseases, today announced the outcome from its End-of-Phase 2 meeting with the FDA, provided a clinical programs update, and reported financial results for the quarter ended March 31, 2024.

“We are pleased to announce that, earlier this quarter, we had a very productive End-of-Phase 2 meeting with the FDA,” said Rick Hawkins, Chairman and CEO of Lumos Pharma. “In this review, the FDA recognized LUM-201’s unique mechanism as a growth hormone secretagogue and acknowledged the use of a placebo-controlled clinical trial design as an appropriate option for a LUM-201 Phase 3 trial. Based on the FDA’s feedback, we plan to move forward with a proposal for a single Phase 3 study that will be a double-blinded, placebo-controlled clinical trial with a 2:1 randomization in approximately 150 patients. We expect to finalize design details with the FDA in the third quarter and to be in position to initiate this trial before the end of this year.”

“In addition to our encouraging engagement with the FDA, we are also very pleased to share updated data from our Phase 2 OraGrowthH trials. These data continue to show that LUM-201 produces a significant increase in growth from baseline in annualized height velocity (AHV) at 6 and 12 months in per protocol analysis. Combined data also suggest durable benefit out to 24 months.”

“We believe these developments have positioned us to advance LUM-201 toward both a Phase 3 registrational trial and potential approval of LUM-201 as the first oral therapeutic for moderate pediatric growth hormone deficiency,” Rick Hawkins concluded.

Recent Highlights

- **End of Phase 2 Meeting Held with FDA**
 - FDA indicated that a placebo-controlled trial design is an appropriate option for a Phase 3 trial for LUM-201. We believe this reflects FDA’s recognition of unique qualities of LUM-201’s mechanism of action as a growth hormone secretagogue.
 - Proposal for a Phase 3 trial to include a 12-month double-blinded, placebo-controlled design with 2:1 randomization, ~150 patients with the placebo-controlled portion of the study lasting six months, which we believe will improve the likelihood of success when compared to a non-inferiority study.
 - Planning is ongoing, and the Company expects to initiate a Phase 3 trial of LUM-201 in Q4 2024, subject to FDA approval.
- **Updated LUM-201 Data from Combined OraGrowthH210 and OraGrowthH212 Trials**

- Additional data continue to show durable LUM-201 treatment effect to 12 and 24 months.
- Full 12-month data from OraGrowthH210 demonstrated LUM-201 produces significant increase in growth from baseline with AHVs of 8.2 cm/yr (N=22) and 7.6 cm/yr (N=21) at 6 and 12 months, respectively, at the 1.6 mg/kg dose vs. 4.7 cm/yr baseline growth (N=13).*
- Full 12-month data from OraGrowthH210 continued to show durable effect to 12 months for all LUM-201 cohorts and 1.6 mg/kg/day as optimal dose to advance to Phase 3.
- Updated combined data from OraGrowthH210 and OraGrowthH212 trials continued to demonstrate LUM-201 AHV durable to 24 months with per protocol-24M (N=12) AHV of 8.1 cm/yr and 7.3 cm/yr at 12 and 24 months, respectively.
- More moderate year-2 decline in AHV of 9.9% for LUM-201 compared to year-2 decline in AHV of 19.7% observed in historical rhGH benchmarks likely due to LUM-201 restoration of GH and IGF-1 to normal levels via amplification of physiologic pulsatile secretion of growth hormone within the natural endocrine feedback loop.
- Investigational safety profile continues to be favorable.
- **Data from Phase 2 OraGrowthH210 and OraGrowthH212 Trials Presented at Medical Meetings in US and Europe**
 - Pediatric Endocrinology Society (PES)
 - 10th International Congress of the Growth Hormone Research Society (GRS)
 - European Congress of Endocrinology (ECE)
 - Data presented at these medical conferences demonstrate that by augmenting the natural pulsatile secretion of growth hormone LUM-201 produces comparable growth to injectable rhGH with significantly less exposure to circulating growth hormone.
- **Additional Data from Phase 2 OraGrowthH Trials to be Presented in Q2 2024**
 - Full 12-Month OraGrowthH212 data, additional analyses of OraGrowthH210 data, and updated combined 24-month data to be presented in Q2 2024
 - Two abstracts accepted for poster presentation at the Endocrine Society (ENDO) Annual Meeting

*Baseline AHV data were not required for enrollment; baseline data available for N=13 subjects.

Financial Results for Quarter Ended March 31, 2024

Cash Position – Lumos Pharma ended the quarter on March 31, 2024, with cash, cash equivalents, and short-term investments totaling \$23.2 million, as compared to \$36.1 million on December 31, 2023. Cash on hand is expected to support operations through Q3 2024, which is inclusive of Phase 3 planning and preparatory activities.

R&D Expenses – Research and development expenses for the quarter ended March 31, 2024 were \$7.2 million, an increase of \$2.9 million compared to the same period in 2023, primarily due to increases of \$2.0 million in licensing expense, \$0.8 million in clinical trial expenses and \$0.2 million in consulting expenses, offset by a decrease of \$0.1 million in personnel-related expenses.

G&A Expenses – General and administrative expenses for the quarter ended March 31, 2024 were \$3.8 million, a decrease of \$0.6 million compared to the same period in 2023, primarily due to decreases of \$0.4 million in licensing expenses, \$0.1 million in travel expenses, \$0.1 million in consulting expenses and \$0.1 million in other expenses, offset by an increase of \$0.1 million in personnel-related expenses.

Net Loss – The net loss for the quarter ended March 31, 2024, was \$10.4 million compared to a net loss of \$7.3 million for the same period in 2023.

Lumos Pharma ended Q1 2024 with 8,107,121 shares outstanding.

Conference Call and Webcast Details

Date: Wednesday, May 15, 2024

Time: 8:30am ET

Dial-in: 1-877-407-9716 or 1-201-493-6779 (International)
Conference ID: 13746447
Dial-in registration (Available 15 minutes prior to scheduled start time): [Click Here](#)
Webcast: [Click Here](#)

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 that our FDA meeting was supportive of a placebo-controlled Phase 3 trial, that we expect to finalize design details with the FDA in the third quarter and to be in position to initiate this trial before the end of this year; that the data continue to show that LUM-201 produces a significant increase in growth from baseline in annualized height velocity (AHV) at 6 and 12 months in per protocol analysis, that combined data also suggest durable benefit out to 24 months, that we plan to move forward with a proposal for a Phase 3 study that will be a double-blinded, placebo-controlled clinical trial with a 2:1 randomization in approximately 150 patients, that we believe this reflects the FDA's recognition of unique qualities of LUM-201's mechanism of action as a growth hormone secretagogue, that we believe these developments have positioned us to advance LUM-201 towards a Phase 3 registrational trial and toward potential approval of LUM-201 as the first oral therapeutic for moderate pediatric growth hormone deficiency, that we believe the study design will improve the likelihood of success when compared to a non-inferiority study, that the investigational safety profile continues to be favorable, that cash on hand is expected to support operations through Q3 2024, which is inclusive of Phase 3 planning and preparatory activities, 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 continued analysis of data from our LUM-201 Trials, the timing and outcome of our future interactions with regulatory authorities including our Type C meeting with the FDA, the timing and ability of Lumos to raise additional equity capital as needed to fund our Phase 3 Trial, our ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the ability to structure our Phase 3 trial in an effective and timely manner, 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 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 Annual Report on Form 10-K for the year ended December 31, 2023, as well as other 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
ir@lumos-pharma.com

Lumos Pharma, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2024	2023
Revenues:		
Royalty revenue	\$ 165	\$ 691
Total revenues	<u>165</u>	<u>691</u>
Operating expenses:		
Research and development	7,248	4,369
General and administrative	3,779	4,357
Total operating expenses	<u>11,027</u>	<u>8,726</u>
Loss from operations	(10,862)	(8,035)
Other income and expense:		
Other income, net	263	119
Interest income	158	570
Other income, net	421	689
Net loss	<u>\$ (10,441)</u>	<u>\$ (7,346)</u>
Net loss per share:		
Basic and diluted	\$ (1.29)	\$ (0.89)
Weighted average number of common shares outstanding:		
Basic and diluted	8,104,905	8,239,941
Other comprehensive income:		
Unrealized gain on short-term investments	—	4
Total comprehensive loss	<u>\$ (10,441)</u>	<u>\$ (7,342)</u>

Lumos Pharma, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	March 31, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 23,179	\$ 35,078
Short-term investments	—	999
Prepaid expenses and other current assets	4,184	3,748
Income tax receivable	181	210
Total current assets	<u>27,544</u>	<u>40,035</u>
Non-current assets:		
Right-of-use asset	534	603
Total assets	<u>\$ 28,078</u>	<u>\$ 40,638</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 569	\$ 890
Accrued expenses	3,552	5,858
Current portion of lease liability	293	282
Total current liabilities	<u>4,414</u>	<u>7,030</u>
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Lease liability	225	303
Total liabilities	<u>10,639</u>	<u>13,333</u>
Commitments and contingencies:		
Stockholders' equity:		
Undesignated preferred stock, \$0.01 par value: Authorized shares - 5,000,000 at March 31, 2024 and December 31, 2023; issued and outstanding shares - 0 at March 31, 2024 and December 31, 2023	—	—
Common stock, \$0.01 par value: Authorized shares - 75,000,000 at March 31, 2024 and December 31, 2023; issued 8,132,007 and 8,125,728 at March 31, 2024 and December 31, 2023, respectively and outstanding shares - 8,107,121 and 8,102,555 at March 31, 2024 and December 31, 2023, respectively	81	81
Treasury stock, at cost, 24,886 and 23,173 shares at March 31, 2024 and December 31, 2023, respectively	(201)	(196)
Additional paid-in capital	189,517	188,937
Accumulated deficit	(171,958)	(161,517)
Total stockholders' equity	<u>17,439</u>	<u>27,305</u>
Total liabilities and stockholders' equity	<u>\$ 28,078</u>	<u>\$ 40,638</u>



Transforming Lives with Rare Focus

End-of-Phase 2 FDA Meeting Review Clinical Update

Q1 2024 Financial Results

May 15, 2024

Forward Looking Statements

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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 plan to have an end-of-phase 2 meeting with the FDA in the first half of 2024 and the anticipated initiation of a Phase 3 program in the second half of 2024, our Phase 2 data providing a clear path to Phase 3 in PGHD, that PEMs enrich trials for patients likely to respond to LUM-201, the expected benefits to LUM-201, 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 continued analysis of data from our LUM-201 Trials, the timing and outcome of our future interactions with regulatory authorities including our end of Phase 2 meeting with the FDA, the timing and ability of Lumos to raise additional equity capital as needed to fund our Phase 3 Trial, our ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the ability to structure and initiate our Phase 3 trial in an effective and timely manner, any statements regarding potential enrollment timelines, the ability to successfully develop our LUM-201 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 Annual Report on Form 10-K for the period ended December 31, 2023, as well as other reports filed with the SEC including our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. 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 presentation.

3/11/2024

Agenda

Welcome

- Lisa Miller, *Vice President of Investor Relations*

Review of Highlights & Clinical Development Program

- Rick Hawkins, *Chief Executive Officer & Chairman*
- John McKew, PhD, *President & Chief Scientific Officer*

Financial Results

- Lori Lawley, *Chief Financial Officer*

Questions & Answers

- Rick Hawkins, *Chief Executive Officer & Chairman*
- John McKew, PhD, *President & Chief Scientific Officer*
- Lori Lawley, *Chief Financial Officer*
- Duke Pitukcheewanont, MD, *Chief Medical Officer*

Summary of Milestones and Additional Phase 2 Data

Milestones & Additional OraGrowth Trial Data

- 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 improve likelihood of success
- Updated OraGrowth 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 demonstrates durability of response to 24 months

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

OraGrowthH210 and OraGrowthH212 Phase 2 Clinical Trials*

- 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

* Topline data as announced November 2023. | Zadik et al Horm Res 1992, 24 hour concentrations calculated based on 12 hour measurement | Adapted from data in Albertsson-Wikland et al JCEM 1994; 24-hour exposures listed reflect absorbance/bioavailability of ~60% of the administered dose

Lumos Submitted Non-Inferiority Study

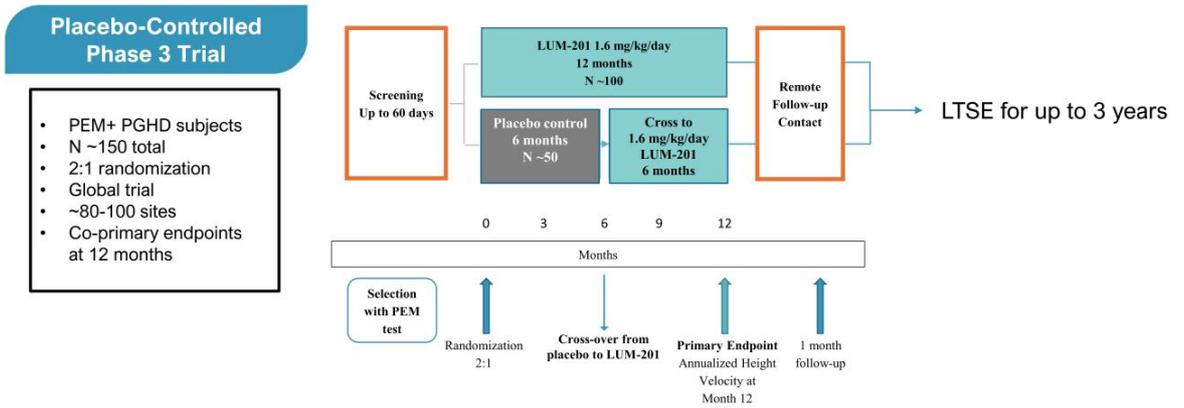
- LUM-201 vs rhGH control
- 12-month duration
- Non-inferiority margin
 - The lower bound of non-inferiority margin must be above the clinically meaningful AHV growth rate

Placebo-Controlled Study

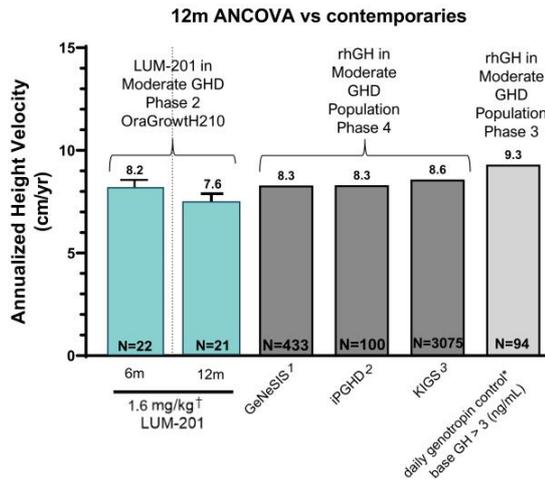
- LUM-201 vs placebo
- 12-month duration
 - Must show clinically meaningful growth rate above the placebo growth rate
 - Potential benefit for placebo arm is an important design consideration
- This presumably arose from their recognition of our **unique** mechanism of action compared to GH

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

12-month, 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



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

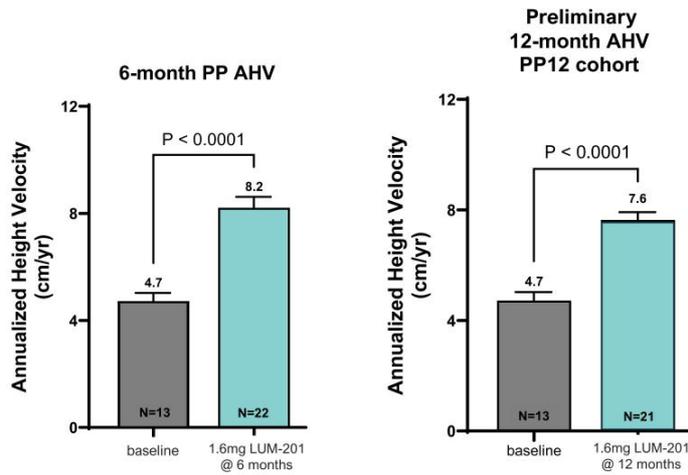
[†] ANCOVA values represent an analysis of covariates incorporating multiple baseline demographic terms. LUM-201 at 6m PP and 12m PP. Twelve-month LUM-201 AHV updated to include preliminary analysis of full 12-month dataset.

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 Somatrogen 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.

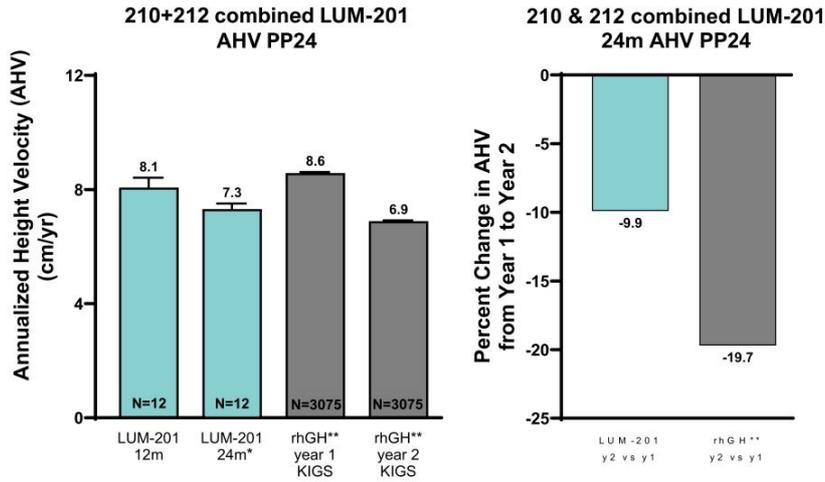
OraGrowthH210: LUM-201 Produces Significant Increase in Growth from Baseline AHV at 6 and 12 Months Per Protocol (PP)



Highlights

- LUM-201 produces a significant increase in growth from baseline
- Durable effect to 12 months
- Minimal drop off in AHV between 6 and 12 months on LUM-201

10 AHV ANCOVA values represent an analysis of covariates incorporating multiple baseline demographic terms. Bars represent Least Squares Mean (LSM). Baseline AHV was not required for enrollment; therefore, baseline AHVs shown represent available data from all OraGrowthH210 cohorts.



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.

Phase 2 Data Presented at Medical Meetings

- Pediatric Endocrine Society (PES)
- Growth Hormone Research Society (GRS)
- European Congress of Endocrinology (ECE)
- Data presented at these medical conferences continue to demonstrate that by augmenting the natural pulsatile secretion of growth hormone, LUM-201 produces comparable growth to injectable rhGH with significantly less exposure to circulating growth hormone.

Updated Phase 2 OraGrowth Data to Be Presented in Q2 2024

- Endocrine Society Annual Meeting (ENDO) – 2 abstracts accepted for presentation
- Full 12-month data from OraGrowthH212 PK/PD Trial
- Updated combined 24-month data from OraGrowthH210 and OraGrowthH212 Trials
- Additional analyses of full 12-month data from OraGrowthH210 Trial

	Q1 2024
R&D Expense	\$7.2M
G&A Expense	\$3.8M
Net Loss	\$10.4M
Cash & Equivalents	\$23.2M
Shares Outstanding	8,107,121



Cash, cash equivalents, & short-term investments to support operations through Q3 2024, inclusive of Phase 3 planning and preparatory activities.

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 therapy• Lead 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 physiology• Orphan Drug Designation in US/EU and issued patents in major markets• IP protection through 2042 in the US for novel formulation	
Clear Proof of Concept	<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 endpoints• Phase 2 data demonstrated LUM-201 produces significant increase in AHV vs baseline• Consistent 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 program• Initiation of Phase 3 trial anticipated Q4 2024	

First oral therapeutic represents potential paradigm shift in treatment of GHD

* Based on gross sales of rhGH worldwide

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

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

