# 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**

August 1, 2024
Date of Report (date of earliest event reported)

# LUMOS PHARMA, INC.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-35342** | **42-1491350** |
|---|---|---|
| (State or other jurisdiction of incorporation or organization) | (Commission File Number) | (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 August 1, 2024, Lumos Pharma, Inc., a Delaware corporation (the "Company"), issued a press release providing an operational update and reporting results for the second quarter ended June 30, 2024 ("Press Release").

A copy of the Press Release and the Second 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 August 1, 2024, entitled "Lumos Pharma Reports Second Quarter 2024 Financial Results and Provides Clinical Development Update" |
| 99.2 | Second 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: August 1, 2024

LUMOS PHARMA, INC.,
a Delaware corporation

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

# Lumos Pharma Reports Second Quarter 2024 Financial Results and Provides Clinical Development Update

*Following Positive End of Phase 2 Meeting with FDA, Company Continues to Advance Plans for Phase 3 Placebo-Controlled Trial of LUM-201 in Moderate Pediatric Growth Hormone Deficiency*

*Expects to Initiate Phase 3 Trial in Q2 2025*

*Company to Host Conference Call Today at 4:30PM ET*

AUSTIN, TX, August 1, 2024 (GLOBE NEWSWIRE) – Lumos Pharma, Inc. (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, today announced financial results for the quarter ended June 30, 2024 and provided a clinical programs update.

“Following our very positive and productive End of Phase 2 Meeting with the FDA, we’ve made substantial progress finalizing our proposal for a Phase 3 double-blinded, placebo-controlled clinical trial with a 2:1 randomization in approximately 150 subjects,” said Rick Hawkins, Chairman and CEO of Lumos Pharma. “Our proposed trial design is informed by the FDA’s prior feedback and recognition of LUM-201's mechanism of action as a growth hormone secretagogue, as well as their acknowledgment that a placebo-controlled clinical trial design is an appropriate option for a LUM-201 Phase 3 trial. We expect to finalize design details with the FDA in the fourth quarter. We are prudently managing our current cash resources and evaluating all strategic opportunities as we advance these plans and expect to be in a position to initiate this trial in the second quarter of 2025.”

“During our second quarter we were also pleased to present new analyses of data from our OraGrowtH212 Trial at ENDO 2024,” continued Mr. Hawkins. “These data further characterized what we believe is LUM-201’s unique ability to augment the natural pulsatile secretion of growth hormone and produce comparable growth to injectable rhGH with significantly less exposure to circulating growth hormone. Furthermore, with additional data, LUM-201 continues to demonstrate a durability of effect out to 24 months, with a more sustainable annualized height velocity than injectable growth hormone has shown in historical studies. We believe these analyses provide additional support for our planned approach to a placebo-controlled Phase 3 trial of LUM-201 in moderate PGHD.”

**Strategic Update**

The Company has engaged Piper Sandler & Co. to assist the Board of Directors in evaluating strategic opportunities to maximize stockholder value as the Company seeks to advance the LUM-201 platform.

**Q2 2024 Highlights**

- **Company Advances Placebo-Controlled Phase 3 Trial Design Suggested by FDA**
  - At End-of-Phase 2 Meeting, FDA indicated that a placebo-controlled trial design is an appropriate option for a Phase 3 trial for LUM-201. We believe such a trial design would significantly improve the probability of success and potential for commercialization of the first oral therapy for moderate Pediatric GHD as compared to a non-inferiority study
  - Placebo-controlled pivotal trial design supported by FDA’s recognition of LUM-201’s mechanism of action as differentiated from injectable growth hormone therapies

- Company continues to advance planning for Phase 3 trial, with initiation now anticipated in Q2 2025, allowing for manufacturing and characterization of LUM-201-matched placebo capsule containing mini-tablets
- Finalization of Phase 3 trial design with FDA anticipated in Q4 2024

- **New Analyses of Phase 2 OraGrowtH212 Trial Presented in Two Posters at ENDO 2024**
  - Data from the posters further support the unique mechanism of action of oral LUM-201 and shows a correlation between the pattern of pulsatile growth hormone secretion and the growth response to LUM-201
  - *Oral LUM-201 Restores Pulsatile Growth Hormone Secretion and Growth Response in Moderate Pediatric Growth Hormone Deficiency (PGHD): Key Discoveries from Phase 2 of OraGrowtH212 Trial (Cassorla, et al)*
  - *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, et al)*

**Financial Results for Quarter Ended June 30, 2024**

**Cash Position** – Lumos Pharma ended the quarter on June 30, 2024, with cash, cash equivalents, and short-term investments totaling $16.8 million, as compared to $36.0 million on December 31, 2023. The Company is managing cash conservatively and believes it has sufficient cash to support operations into the first quarter of 2025.

**R&D Expenses** – Research and development expenses were $4.6 million, a decrease of $1.4 million for the quarter ended June 30, 2024 compared to the same period in 2023, primarily due to decreases of $1.1 million in contract manufacturing expenses, $0.3 million in personnel-related expenses and $0.2 million in clinical trial expenses, offset by an increase of $0.2 million in consulting expenses.

**G&A Expenses** – General and administrative expenses were $3.7 million, a decrease of $0.5 million compared to the same period in 2023, primarily due to decreases of $0.2 million in personnel-related expenses, $0.1 million in travel expenses, $0.1 million in consulting expenses and $0.1 million in other expenses.

**Net Loss** – The net loss for the quarter ended June 30, 2024, was $7.6 million compared to a net loss of $8.9 million for the same period in 2023.

Lumos Pharma ended Q2 2024 with 8,123,186 shares outstanding.

**Conference Call and Webcast Details**
Date: Tuesday, August 1, 2024
Time: 4:30PM ET
Dial-in: 1-866-652-5200 or 1-412-317-6060 (International)
Conference ID: 10191274
Dial-in registration (Available 15 minutes prior to scheduled start time): Click Here
Dial-in registration passcode: 2835283
Webcast: Click Here

Investors and the general public are invited to listen to the conference call. To avoid delays, we encourage participants to dial into the conference call ten minutes ahead of the scheduled start time. The webcast link may also be found in the “Investors & Media” section of the Lumos Pharma website, under “Events & Presentations.” A replay will be available after the date of the call and may be accessed through the same link above or found on our website.

**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 our finalization of design details for a Phase 3 clinical trial with the FDA in the fourth quarter of 2024 and our positioning to initiate this trial in the second quarter of 2025, that we believe new analyses provide additional support for our planned approach to a placebo-controlled Phase 3 trial of LUM-201 in moderate PGHD, that we believe the trial design would improve the likelihood of success when compared to a non-inferiority study, that cash on hand is expected to support operations into Q1 2025, 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 obtain FDA approval of, initiate and advance a pivotal Phase 3 trial, as well as advance our clinical and corporate strategy in general, our ability to obtain the capital needed to fund a Phase 3 trial and other business operations, our ability to forecast and manage future cash utilization and reserves needed for contingent future liabilities and business operations, the ability to successfully develop our product candidate 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 year ended December 31, 2023 and Quarterly Reports on Form 10-Q for the periods ended March 31 and June 30, 2024, 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:

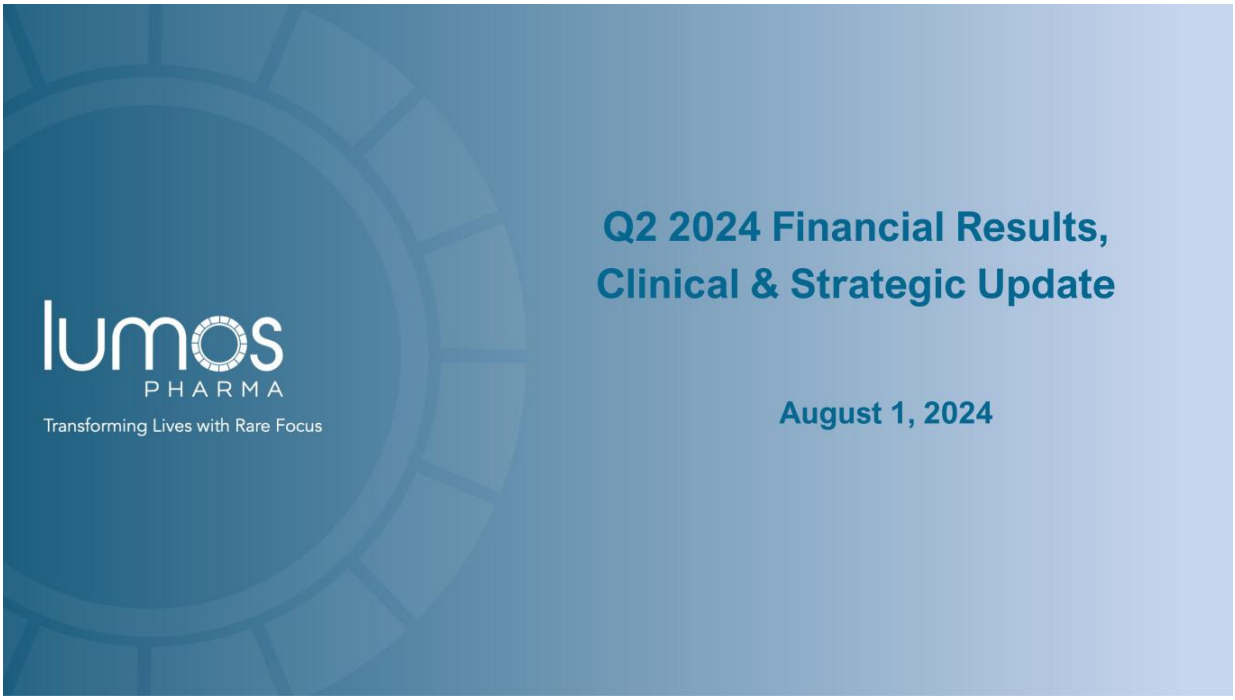
Lisa Miller
Lumos Pharma Investor Relations
512-792-5454
ir@lumos-pharma.com

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **2023** |
| Revenues: | | | | |
| Royalty revenue | $ 488 | $ 527 | $ 653 | $ 1,218 |
| Total revenues | 488 | 527 | 653 | 1,218 |
| Operating expenses: | | | | |
| Research and development | 4,629 | 6,024 | 11,877 | 10,393 |
| General and administrative | 3,682 | 4,146 | 7,461 | 8,503 |
| Total operating expenses | 8,311 | 10,170 | 19,338 | 18,896 |
| Loss from operations | (7,823) | (9,643) | (18,685) | (17,678) |
| Other income and expense: | | | | |
| Other income, net | 202 | 124 | 465 | 243 |
| Interest income | 70 | 559 | 228 | 1,129 |
| Other income, net | 272 | 683 | 693 | 1,372 |
| Net loss before taxes | $ (7,551) | $ (8,960) | $ (17,992) | $ (16,306) |
| Income tax benefit | — | 29 | — | 29 |
| Net loss | $ (7,551) | $ (8,931) | $ (17,992) | $ (16,277) |
| | | | | |
| Net loss per share: | | | | |
| Basic and diluted | $ (0.93) | $ (1.09) | $ (2.22) | $ (1.98) |
| | | | | |
| Weighted average number of common shares outstanding: | | | | |
| Basic and diluted | 8,112,566 | 8,164,603 | 8,107,528 | 8,205,625 |
| | | | | |
| Other comprehensive income: | | | | |
| Unrealized loss on short-term investments | — | (6) | — | (2) |
| Total comprehensive loss | $ (7,551) | $ (8,937) | $ (17,992) | $ (16,279) |

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

| | June 30, 2024 (unaudited) | December 31, 2023 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 16,799 | $ 35,078 |
| Short-term investments | — | 999 |
| Prepaid expenses and other current assets | 3,925 | 3,748 |
| Income tax receivable | 168 | 210 |
| Total current assets | 20,892 | 40,035 |
| Non-current assets: | | |
| Right-of-use asset | 463 | 603 |
| Total assets | $ 21,355 | $ 40,638 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 337 | $ 890 |
| Accrued expenses | 4,294 | 5,858 |
| Current portion of lease liability | 304 | 282 |
| Total current liabilities | 4,935 | 7,030 |
| Long-term liabilities: | | |
| Royalty obligation payable to Iowa Economic Development Authority | 6,000 | 6,000 |
| Lease liability | 145 | 303 |
| Total liabilities | 11,080 | 13,333 |
| Commitments and contingencies: | | |
| Stockholders' equity: | | |
| Undesignated preferred stock, $0.01 par value: Authorized shares - 5,000,000 at June 30, 2024 and December 31, 2023; issued and outstanding shares - 0 at June 30, 2024 and December 31, 2023 | — | — |
| Common stock, $0.01 par value: Authorized shares - 75,000,000 at June 30, 2024 and December 31, 2023; issued 8,151,900 and 8,125,728 at June 30, 2024 and December 31, 2023, respectively and outstanding shares - 8,123,186 and 8,102,555 at June 30, 2024 and December 31, 2023, respectively | 81 | 81 |
| Treasury stock, at cost, 28,714 and 23,173 shares at June 30, 2024 and December 31, 2023, respectively | (212) | (196) |
| Additional paid-in capital | 189,915 | 188,937 |
| Accumulated deficit | (179,509) | (161,517) |
| Total stockholders' equity | 10,275 | 27,305 |
| Total liabilities and stockholders' equity | $ 21,355 | $ 40,638 |


lumos
PHARMA
Transforming Lives with Rare Focus
Q2 2024 Financial Results,
Clinical & Strategic Update
August 1, 2024

# Forward Looking Statements

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8.1.2024

# 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*

## Clinical and Strategic Update

| | |
|---|---|
| **Positive EOP2 Meeting with FDA** | • FDA supportive of registrational path forward<br>• FDA recognized LUM-201, a growth hormone secretagogue, as a novel growth promoter<br>• 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 Q2 2025** | • Phase 3 initiation expected in Q2 2025<br>• Proposed placebo-controlled trial protocol expected to be finalized in Q4 2024<br>• Placebo-controlled design should improve likelihood of success |
| **Exploring All Opportunities** | • Engaged investment bank to assist the Board of Directors in exploring all strategic opportunities and advance LUM-201<br>• Our regular business development activities have garnered significant interest in opportunity for LUM-201 in multiple markets worldwide<br>• LUM-201 has potential to be first oral therapeutic in ~$5 billion global injectable GH market |

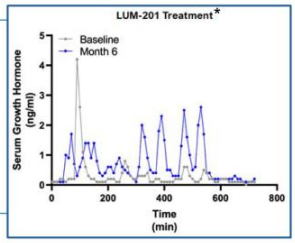
**Advancing LUM-201, potentially the first oral therapeutic for the treatment of GHD**


EOP2: End of Phase 2 meeting GHD: Growth Hormone Deficiency

# Data Presented at Medical Conferences Highlight Oral LUM-201 Potential in PGHD

## ENDO 2024

- LUM-201's pulsatile pattern of growth hormone secretion is key in eliciting growth response
- Pulsatile mechanism allows oral LUM-201 to produce growth comparable to injectable rhGH but at only ~20% of the exposure to circulating growth hormone




## PES 2024

- Oral LUM-201 produces comparable growth to that achieved by injectable rhGH in moderate PGHD as demonstrated in multiple historical datasets

## GRS and ECE 2024

- Data demonstrate oral LUM-201 restores natural pulsatile secretion of growth hormone and growth in moderate PGHD patients

* OraGrowthH212 PK/PD Trial: GH secretion in PGHD subject over 12 hours: at baseline and at 6 months on LUM-201



ENDO: Endocrine Society Annual Meeting PES: Pediatric Endocrine Society Annual Meeting GRS: Growth Hormone Research Society ECE: European Congress of Endocrinology

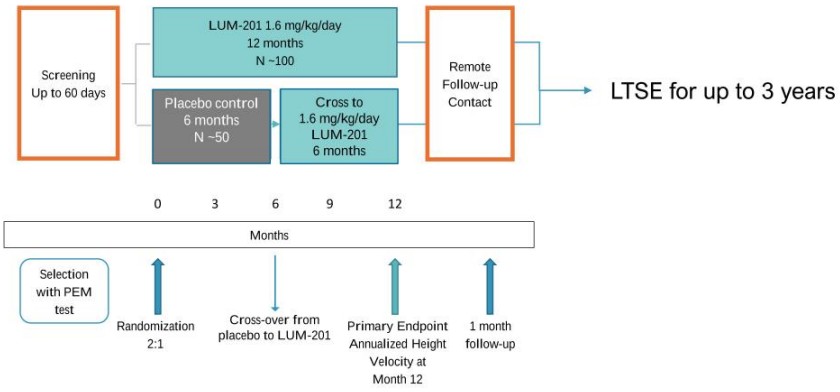
# Proposed Placebo-Controlled Phase 3 Trial Design



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

**Placebo-Controlled Phase 3 Trial**

- PEM+ PGHD subjects
- N ~150 total
- 2:1 randomization
- Global trial
- ~80-100 sites
- Co-primary endpoints at 12 months
- Trial initiation anticipated in Q2 2025




**Co-Primary Endpoints:**

1) Demonstrate superiority of growth on LUM-201 at 12 months vs Placebo at 12 months (6 months annualized)
2) Ensure AHV of LUM-201 at 12 months has a lower bound of the 95% confidence interval above 6.7 cm/yr, the threshold for clinically meaningful growth previously agreed upon with the FDA

LTSE = Long-term Safety Extension
AHV = Annualized Height Velocity

## Lumos Pharma Pro Forma Financial Information as of June 30, 2024

*Values in USD*

| | Q2 2024 |
|---|---|
| R&D Expense | $4.6M |
| G&A Expense | $3.7M |
| Net Loss | $7.6M |
| | |
| Cash & Equivalents | $16.8M |
| Shares Outstanding | 8,123,186 |


**Cash, cash equivalents, & short-term investments to support operations into Q1 2025.**

# Investment Thesis

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

| | |
|---|---|
| **Attractive Market Opportunity** | • Global growth hormone (GH) market of ~$4.7 billion is primed for conversion to oral therapy<br>• Lead indication, PGHD, is ~$1.5 billion global opportunity[1]<br>• Market research supports rapid conversion to oral and potential expansion opportunities[2] |
| **Novel Asset with Unique MOA** | • Oral LUM-201 pulsatile GH secretion MOA takes advantage of natural physiology<br>• Orphan Drug Designation in US/EU and issued patents in major markets<br>• IP protection through 2042 in the US for novel formulation |
| **Clear Proof of Concept** | • PEM strategy de-risks patient selection, identifying likely LUM-201 responders[3]<br>• Phase 2 trials met all primary and secondary endpoints<br>• Phase 2 data demonstrated LUM-201 produces significant increase in AHV vs baseline<br>• Consistent PK/PD and attractive investigational safety profile to date in > 1,300 subjects |
| **Regulatory Path Clarity** | • Positive End-of-Phase 2 meeting with FDA held early Q2 2024 regarding Phase 3 program<br>• Initiation of Phase 3 trial anticipated Q2 2025 |

**First oral therapeutic represents potential paradigm shift in treatment of GHD**

[1] Based on gross sales of rhGH worldwide
[2] Initial Primary Research of PGHD Market conducted for Lumos by Triangle Insights
[3] 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