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

November 3, 2021
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 November 3, 2021, Lumos Pharma, Inc., a Delaware corporation (the “Company”), issued a press release providing an operational update and reporting results for the third quarter ended September 30, 2021 ("Press Release").

A copy of the Press Release and the Third Quarter 2021 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 November 3, 2021, entitled "Lumos Pharma Reports Third Quarter 2021 Financial Results and Provides Clinical and Corporate Updates"
99.2	Third Quarter 2021 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: November 3, 2021

LUMOS PHARMA, INC.,
a Delaware corporation

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

FOR IMMEDIATE RELEASE

Lumos Pharma Reports Third Quarter 2021 Financial Results and Provides Clinical Updates

- *Majority of OraGrowtH210 Trial sites are open with recent and imminent openings representing historically high enrollment sites*
- *Six-month primary outcome data readout from OraGrowtH210 expected 2H 2023*

AUSTIN, TX, November 3, 2021 - Lumos Pharma, Inc. (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, announced financial results for the third quarter ending September 30, 2021 and provided an update on clinical programs.

“During our third quarter we continued to advance our LUM-201 program for the treatment of pediatric growth hormone deficiency (PGHD), with the opening of a number of new OraGrowtH210 Trial sites,” said Rick Hawkins, Chairman and CEO of Lumos Pharma. “The screening and enrollment for both our OraGrowtH210 and OraGrowtH212 Trials are progressing well. We continue to expect the primary outcome data readout for our OraGrowtH210 trial in the second half of 2023. Beyond PGHD, we believe LUM-201 represents a pipeline-in-a-product and are encouraged by discussions with KOLs regarding the potential to expand our LUM-201 platform into other indications currently treated by injectable growth hormone.”

Clinical Update:

OraGrowtH210 Trial of LUM-201 in PGHD

Enrollment in the Phase 2 OraGrowtH210 Trial of LUM-201 in PGHD continues, with the majority of the approximately 50 planned sites activated and open for enrollment. OraGrowtH210 is a global clinical trial and is evaluating orally administered LUM-201 in approximately 80 patients diagnosed with PGHD. The objective of the trial is to identify the optimal dose of LUM-201 based on annualized height velocity to be used in a Phase 3 registration trial and to prospectively confirm the preliminary validation of our Predictive Enrichment Marker (PEM) strategy. The Company continues to anticipate six-month data read-out for the OraGrowtH210 Trial in the second half of 2023, with additional 12-month data to be collected.

OraGrowtH212 Trial of LUM-201 in PGHD Initiated Q2 2021

The OraGrowtH212 Trial was initiated in June and is also continuing to enroll patients. OraGrowtH212 is a single site, open-label trial evaluating the pharmacokinetic (PK) and pharmacodynamic (PD) effects of LUM-201 in up to 24 PGHD patients at two dose levels, 1.6 and 3.2 mg/kg/day. Given the open-label design of this trial, the Company has the ability to perform an interim analysis at its discretion. The objective of OraGrowtH212 is to confirm prior clinical data demonstrating the amplified pulsatile release of endogenous growth hormone unique to LUM-201 and its potential for this mechanism of action to contribute to efficacy in PGHD. The primary endpoint is six months of PK/PD and height velocity data, with additional 12-month data to be captured.

LUM-201 Life-Cycle Management

Injectable recombinant human growth hormone (rhGH) and derivative products are currently approved for multiple indications, including PGHD. LUM-201, through its unique mechanism of promoting increased secretion of endogenous GH, may have the potential to be efficacious in many of these indications. Lumos Pharma is in advanced discussions with key opinion leaders and our Clinical and Scientific Advisory Board to expand our LUM-201 pipeline. The Company is actively reviewing the pathway for LUM-201 in other indications including Turner Syndrome, Prader-Willi Syndrome, Idiopathic Short Stature (ISS), and Children Born Small for Gestational Age (SGA).

Financial Results for the Quarter Ended September 30, 2021

- Cash Position – Lumos Pharma ended the third quarter on September 30, 2021, with cash and cash equivalents totaling $100.7 million compared to $98.7 million on December 31, 2020. Cash on hand as of the end of Q3 2021 is expected to support operations through the primary outcome data readout from OraGrowtH210 and OraGrowtH212 Trials.
- R&D Expenses – Research and development expenses were $4.1 million, an increase of $2.0 million for the three months ended September 30, 2021 compared to the same period in 2020, primarily due to increases of $1.8 million in clinical trial and contract manufacturing expenses, $0.4 million in personnel-related expenses and $0.1 million in stock compensation expenses, offset by a decrease of $0.3 million in supplies and other expenses.
- G&A Expenses – General and administrative expenses were $3.4 million, a decrease of $1.8 million for the three months ended September 30, 2021, as compared to the same period in 2020, primarily due to decreases of $1.3 million in personnel-related expenses, $0.3 million in legal, consulting and other expenses and $0.2 million in operating expenses for insurance, rent, supplies, and depreciation.
- Net Loss – The net loss for the third quarter ended September 30, 2021 was $7.5 million compared to net income of $1.8 million for the same period in 2020.
- Lumos Pharma ended Q3 2021 with 8,357,391 shares outstanding.

Conference Call and Webcast Details

The Company has scheduled a conference call and webcast for 4:30 p.m. ET today to discuss its financial results and to give an update on clinical programs. There will also be a question-and-answer session following management's prepared remarks.

Access to the live conference call is available five minutes prior to the start of the call by dialing (855) 469-0612 (U.S.) or (484) 756-4268 (international). The conference call will be webcast live and a link to the webcast can be accessed through the Lumos Pharma website at https://lumos-pharma.com/ in the "Investors & Media" section under "Events and Presentations" or through this link: https://edge.media-server.com/mmc/p/yxhoo2hz. To ensure a timely connection, it is recommended that users register at least 10 minutes prior to the scheduled webcast. A replay of the call will be available approximately two hours after the completion of the call and can be accessed by dialing (855) 859-2056 (U.S.) or (404) 537-3406 (international) and using the passcode 2891824. The replay will be available for two weeks from the date of the call.

About Lumos Pharma

Lumos Pharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of therapeutics for rare diseases. Lumos Pharma was founded and is led by a management team with longstanding experience in rare disease drug development and received early funding from leading healthcare investors, including Deerfield Management, a fund managed by Blackstone Life Sciences, Roche Venture Fund, New Enterprise Associates (NEA), Santé Ventures, and UCB. Lumos Pharma's lead therapeutic candidate is LUM-201, an oral growth hormone stimulating small molecule, currently being evaluated in a Phase 2 clinical trial, the OraGrowtH210 Trial, and a PK/PD trial, the OraGrowtH212 Trial, for the treatment of Pediatric Growth Hormone Deficiency (PGHD). If approved by the FDA, LUM-201 would provide an orally administered alternative to recombinant growth hormone injections that PGHD patients otherwise endure for many years of treatment.

LUM-201 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 screening and enrollment for both our OraGrowthH210 and OraGrowthH212 Trials progressing well, expecting the primary outcome data readout for our OraGrowthH210 trial in the second half of 2023, the potential to expand our LUM-201 platform into other indications, anticipated market reception to our treatment regimen for PGHD and other indications, plans related to initiation and execution of clinical trials; plans related to moving additional indications into clinical development; future financial performance, results of operations, cash position and sufficiency of capital resources to fund our operating requirements through the primary outcome data readout from OraGrowthH210 and OraGrowthH212 Trials, 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 in the "Risk Factors" section and elsewhere in Lumos Pharma's Annual Report on Form 10-K for the year ended December 31, 2020, as well as other reports filed with the SEC including our Quarterly Reports on Form 10-Q. 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:

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Lumos Pharma Investor Relations
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ir@lumos-pharma.com

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Licensing and collaboration revenue	—	74	10	128
Total revenues	—	74	10	128
Operating expenses:				
Research and development	4,112	2,075	12,885	6,743
General and administrative	3,385	5,156	11,903	12,634
Total operating expenses	7,497	7,231	24,788	19,377
Loss from operations	(7,497)	(7,157)	(24,778)	(19,249)
Other income and expense:				
Other income, net	7	6,322	19	6,482
Interest income	2	168	7	246
Interest expense	—	—	(37)	(48)
Other (expense) income, net	9	6,490	(11)	6,680
Net loss before taxes	(7,488)	(667)	(24,789)	(12,569)
Income tax benefit	—	2,432	—	9,321
Net income (loss)	$ (7,488)	$ 1,765	$ (24,789)	$ (3,248)
Accretion of preferred stock to current redemption value	—	—	$ —	(651)
Net income (loss) attributable to common shareholders	$ (7,488)	$ 1,765	$ (24,789)	$ (3,899)
Net income (loss) per share of common stock				
Basic and diluted	$ (0.90)	$ 0.21	$ (2.97)	$ (0.62)
Weighted average number of common shares outstanding				
Basic	8,357,391	8,293,312	8,333,017	6,267,576
Diluted	8,357,391	8,486,804	8,333,017	6,267,576

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 100,650	$ 98,679
Prepaid expenses and other current assets	4,988	3,506
Income tax receivable	116	115
Other receivables	—	26,149
Total current assets	105,754	128,449
Non-current assets:		
Property and equipment, net	75	335
Right-of-use asset	636	249
Total non-current assets	711	584
Total assets	$ 106,465	$ 129,033
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 149	$ 244
Accrued expenses	5,555	5,898
Current portion of lease liability	349	319
Total current liabilities	6,053	6,461
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Lease liability	288	—
Total long-term liabilities	6,288	6,000
Total liabilities	12,341	12,461
Commitments and contingencies:		
Stockholders' equity:		
Undesignated preferred stock, $0.01 par value: Authorized shares - 5,000,000 at September 30, 2021 and December 31, 2020; issued and outstanding shares - 0 at September 30, 2021 and December 31, 2020	$ —	$ —
Common stock, $0.01 par value: Authorized shares - 75,000,000 at September 30, 2021 and December 31, 2020; issued 8,366,819 and 8,305,269 at September 30, 2021 and December 31, 2020, respectively and outstanding 8,357,391 and 8,305,269 at September 30, 2021 and December 31, 2020, respectively	$ 83	$ 83
Treasury stock, at cost, 9,428 and 0 at September 30, 2021 and December 31, 2020, respectively	$ (114)	$ —
Additional paid-in capital	$ 184,935	$ 182,480
Accumulated deficit	$ (90,780)	$ (65,991)
Total stockholders' equity	94,124	116,572
Total liabilities and stockholders' equity	$ 106,465	$ 129,033


lumos
PHARMA
Third Quarter 2021
November 3, 2021

Forward Looking Statements

This presentation contains forward-looking statements of Lumos Pharma, Inc. (the “Company”) 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. The words “forecast,” “projected,” "guidance," "upcoming," "will," “would,” "plan," “intend,” "anticipate," "approximate," "expect," “potential,” “imminent,” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, the ability of prior research results to forecast the performance of therapeutic agents in the clinic, anticipated business development activities, anticipated market reception to our treatment regimen for PGHD and other indications, plans related to initiation and execution of clinical trials; plans related to moving additional indications into clinical development; future financial performance, results of operations, cash position and sufficiency of capital resources to fund its operating requirements; and any other statements other than statements of historical fact.

Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that the Company makes due to a number of important factors, including the effects of pandemics or other widespread health problems, the outcome of our future interactions with regulatory authorities, our ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the ability to obtain the necessary patient enrollment for our product candidate in a timely manner, the ability to successfully develop our product candidate, the timing and ability of Lumos to raise additional equity capital as needed and other risks that could cause actual results to differ materially from those matters expressed in or implied by such forward-looking statements as discussed in "Risk Factors" and elsewhere in Lumos Pharma’s Annual Report on Form 10-K for the year ended December 31, 2020 and other reports filed with the SEC.

The forward-looking statements in this presentation represent the Company’s views as of the date of this presentation. The Company anticipates that subsequent events and developments will cause their views to change. However, while it may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing the Company’s views as of any date subsequent to the date of this presentation. 11.3.21

Agenda

Welcome

- Lisa Miller, *Senior Director of Investor Relations*

Clinical Development Update

- Rick Hawkins, *Chief Executive Officer & Chairman*

Financial Results

- Lori Lawley, *Chief Financial Officer*

Question & Answer Session

- Rick Hawkins, *Chief Executive Officer & Chairman*
- John McKew, PhD, *President & Chief Scientific Officer*
- David B. Karpf, MD, *Chief Medical Officer*
- Lori Lawley, *Chief Financial Officer*

LUM-201 Program Pipeline

	Study	Pre-Clinical	Phase 1	Phase 2	Phase 3	Status
LUM-201 (Ibutamoren) In PGHD	Phase 2	OraGrowtH210 TRIAL				Ongoing Phase 2 trial with 6-month data readout expected in second half of 2023
	Long-term extension	OraGrowtH211 TRIAL				Proposed long-term extension study for OraGrowtH Trials
	PK/PD trial	OraGrowtH212 TRIAL				Pharmacokinetic/Pharmacodynamic (PK/PD) trial open and recruiting patients

Lumos is evaluating additional indications for LUM-201 for Phase 2 studies

- Small for Gestational Age
- Prader-Willi Syndrome
- Turner Syndrome
- Idiopathic Short Stature

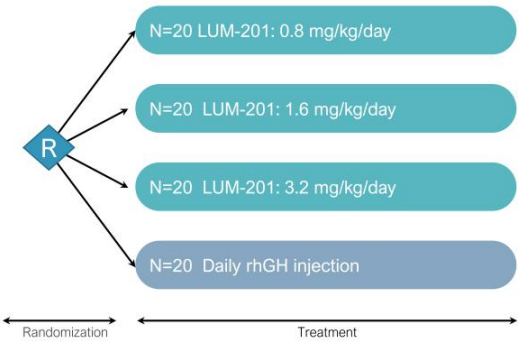
PGHD Pediatric Growth Hormone Deficiency

OraGrowthH210 Trial: Phase 2 Trial in PGHD

OraGrowthH210 TRIAL

- n = 80
- PEM(+) PGHD patients
- Inclusion: stim GH ≥ 5ng/ml and baseline IGF-1 > 30ng/ml
- rhGH treatment naïve
- ~50 trial sites US & International
- Trial opened Q4 2020

Primary Outcome Data – at 6 months
Total Study Duration – 12 months



Screening | Randomization | Treatment

Objectives

Primary Endpoint:
- Annualized Height Velocity (AHV)

Goals:
- Prospectively confirm utility of PEM strategy
- Determine optimal dose for Phase 3

Anticipate primary outcome data readout for OraGrowthH210 Trial 2H2023

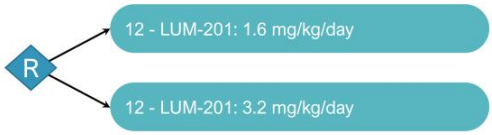
*Proposed protocol amendment

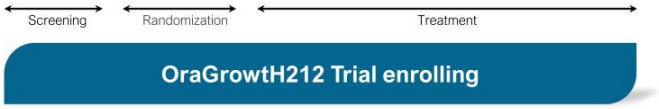
OraGrowtH212 Trial: Pharmacokinetic / Pharmacodynamic Trial in PGHD

OraGrowtH212 TRIAL

- n = 24
- Open-label study
- PGHD patients
- rhGH-treatment naïve
- 12-month dosing
- Single, specialized clinical site
- Q10 minute GH sampling for 12 hours

Primary Outcome Data – at 6 months
Total Study Duration – 12 months





OraGrowtH212 Trial enrolling

Objectives

Primary Endpoints:

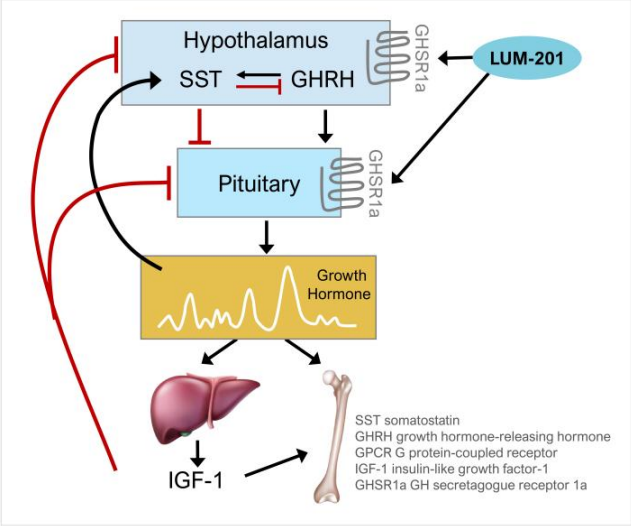
- Assess LUM-201 effect on endogenous GH pulsatility and Annualized Height Velocity (AHV)
- Evaluate PK/PD in children

Goals:

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

*Proposed protocol amendment

LUM-201 Stimulates Endogenous GH Secretion vs. Exogenous rhGH Injection



- LUM-201 is an oral growth hormone (GH) secretagogue
- Agonist of GPCR GH Secretagogue Receptor 1a (GHSR1a)
- Stimulates release of GH[1]
- Increases the amplitude of endogenous pulsatile GH secretion[2,3]
- Stimulatory effect is regulated by endogenous GH/IGF-1 feedback
- Differentiated from bolus 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

Secure Cash Position

Metric	Position
Cash balance September 30, 2021	$100.7 million
Strong financial position	Cash runway through primary outcome data for OraGrowthH210 & OraGrowthH212 Trials
Shares outstanding as of September 30, 2021	~ 8.4 million

Cash balance to support current operations through primary outcome data readouts for OraGrowthH210 and OraGrowthH212 Trials

Investment Highlights

Late-stage Rare Disease Asset	• Novel **oral** therapeutic asset, **LUM-201**, for growth hormone deficiency disorders • Phase 2 OraGrowthH210 Trial in PGHD – Enrolling with primary outcome data 2H2023 • PK/PD OraGrowthH212 Trial in PGHD – Open-label trial currently enrolling
Pipeline in a Product	• Current market for initial indication, PGHD, is $1.2 billion* • Multiple potential follow-on indications represent up to additional $2.2 billion • Potential to disrupt injectable treatment regimen for significant subset of patients
Experienced Management	• Established track record of performance in rare disease drug development • Business development acumen with expertise in licensing pipeline assets
Solid Financial Position	• Cash balance of $100.7 million at close of Q3 2021 • Cash runway through primary outcome data for OraGrowthH210 & OraGrowthH212 Trials • High quality, long-term investors

PGHD = Pediatric Growth Hormone Deficiency
* USA, Germany, France, Italy, Spain, UK, Japan (Grandview Research, Growth Hormone Market Forecast, 2019)