UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 21, 2019

OPKO Health, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-33528**	**75-2402409**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4400 Biscayne Blvd. Miami Florida	**33137**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (305) 575-4100

Not Applicable
Former name or former address, if changed since last report

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:

☐ 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	OPK	NASDAQ Global Select 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 7.01. Regulation FD

On September 21, 2019, OPKO Health, Inc. (the "Company") presented four year results from a phase 2 extension study for once weekly Somatrogon (hGH-CTP) in a poster presentation at the 58th Annual Meeting of the European Society for Paediatric Endocrinology, held in Vienna Austria. The data presented included long term safety and efficacy results from the Company's phase 2 open label extension study in children with Growth Hormone Deficiency.

A copy of the poster, entitled "Long-Term Safety of a Once-Weekly Somatrogon (hGH-CTP): 4-Year Results of a Phase 2 Extension Study in Children with Growth Hormone Deficiency", is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information included herein and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

ITEM 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Poster presented at 58th Annual Meeting of the ESPE

Exhibit Index

Exhibit No.	Description
99.1	Poster presented at 58th Annual Meeting of the ESPE

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.

OPKO Health, Inc.

By: /s/ Adam Logal
Name: Adam Logal
Title: Senior Vice President, Chief Financial Officer

Date: September 23, 2019

Long-Term Safety of a Once-Weekly Somatrogon (hGH-CTP): *4-Year Results of a Phase 2 Extension Study in Children with Growth Hormone Deficiency*

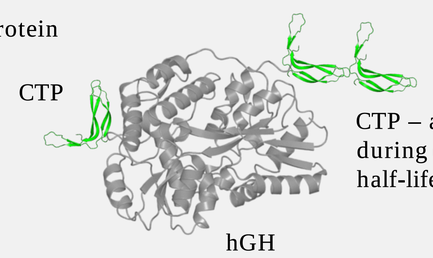
Nataliya Zelinska[1], Yulia Skorodok[2], Oleg Malievsky[3], Violeta Iotova[4], Ron G. Rosenfeld[5], Zvi Zadik[6], Shelly Vander[7], and Aleksandra Pastrak[8]

[1]Ukrainian Children Specialized Clinical Hospital, Kyev; [2]St. Petersburg State Pediatric Medical University, St. Petersburg; [3]Bashkir State Medical University, Ufa; [4]UMHAT, Varna; [5]Oregon Health & Science University, Oregon, USA; [6]Kaplan Medical Center, Rehovot, Israel; [7]OPKO Biologics, Kiryat Gat, Israel; [8]OPKO Health, Miami.

BACKGROUND

Once-daily growth hormone (GH) therapy is an effective treatment for children with growth hormone deficiency (GHD), but a decrease in compliance with prolonged treatment can reduce the treatment benefits. Somatrogon, also known as MOD-4023, is a long-acting recombinant protein consisting of human growth hormone (hGH) and three copies of C-terminal peptide (CTP). It is a new molecular entity with receptor binding properties and a mechanism of action analogous to hGH. A once-weekly somatrogon (hGH-CTP), is being developed to reduce the treatment burden of daily dosing for children and caregivers and potentially improve compliance and long-term efficacy [1].

Figure 1. Long-acting CTP-hGH protein



CTP – a natural peptide created during evolution to enhance the half-life of hCG

OBJECTIVES

The objective of the open-label extension (OLE) Phase 2 study was to demonstrate the long-term impact of once-weekly somatrogon treatment beyond the initial 12 months of the primary study. Key objectives of this report included evaluation of safety, local tolerability, growth outcome and immunogenicity in patients treated with somatrogon for a period of up to 4 years in the OLE.

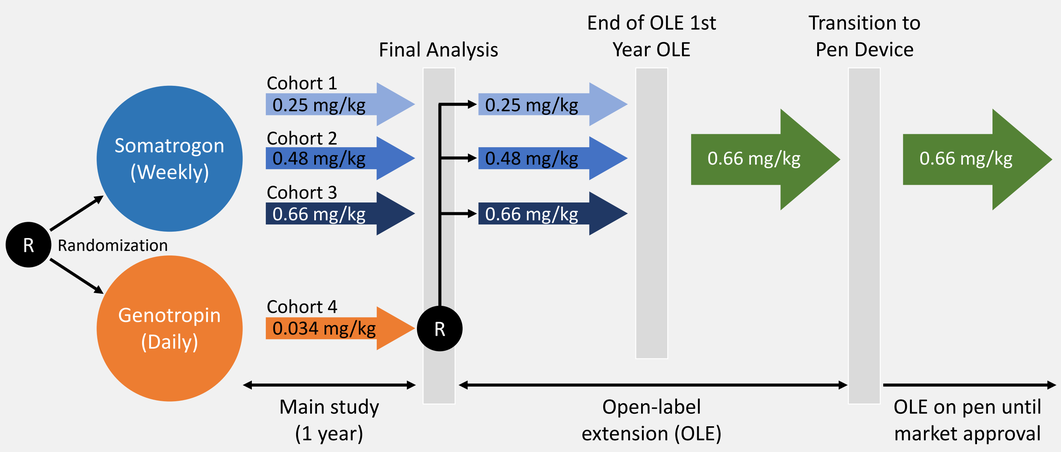
METHODS

The OLE phase 2 study was a continuation of a randomized 12-month study that investigated the efficacy, safety, and tolerability of 3 dose levels of somatrogon, administered weekly (0.25, 0.48, or 0.66 mg/kg/week) compared to daily r-hGH (Genotropin® 0.034 mg/kg/day) in pre-pubertal pediatric patients with GHD [2].

Forty-eight children with GHD that completed the main Phase 2 study continued in the OLE. Subjects who were randomized to somatrogon in the main study continued with the same dose of somatrogon; subjects who were originally assigned to daily Genotropin® were randomly re-assigned to one of the three somatrogon dose levels. Following the first 12-months of treatment in the OLE all subjects were transitioned to 0.66 mg/kg/week.

Subjects were treated with somatrogon (frozen vial) for up to 4 years until transfer to a somatrogon pen device. Forty subjects (83%) are continuing in OLE on pen device (Figure 2). Top line results for up to 4 years of treatment in the OLE are reported.

Figure 2. Study design (*ClinicalTrials.gov: NCT01592500*)



RESULTS: Demographics at the Start of Open Label Extension

	All (N=48)
Mean age (SD), years	7.65 (2.104)
Gender, male (%)	32 (66.7)
Race, white (%)	45 (93.8)
Pubertal status Tanner I (%)	47 (97.9)

	All (N=48)
Mean weight (SD), kg	20.39 (5.150)
Mean height (SD), cm	112.6 (11.07)
Mean BMI (SD), kg/m^2	15.82 (1.740)
Mean IGF-1 SDS (SD), Z	0.03 (1.176)

RESULTS: OLE Safety Years 1 to 4

Treatment-emergent adverse events (TEAEs)	All subjects (N=48), n (%) [AEs]
Any TEAEs	38 (79.2) [190]
Serious TEAEs	3 (6.3) [4]
TEAEs related to study drug	4 (8.3) [11]
TEAEs leading to study discontinuation	1 (2.1) [1]

TEAEs > 5% of subjects	All (N=48)
U. resp. tract infection	13 (27.1)
Bronchitis	9 (18.8)
Rhinitis	5 (10.4)

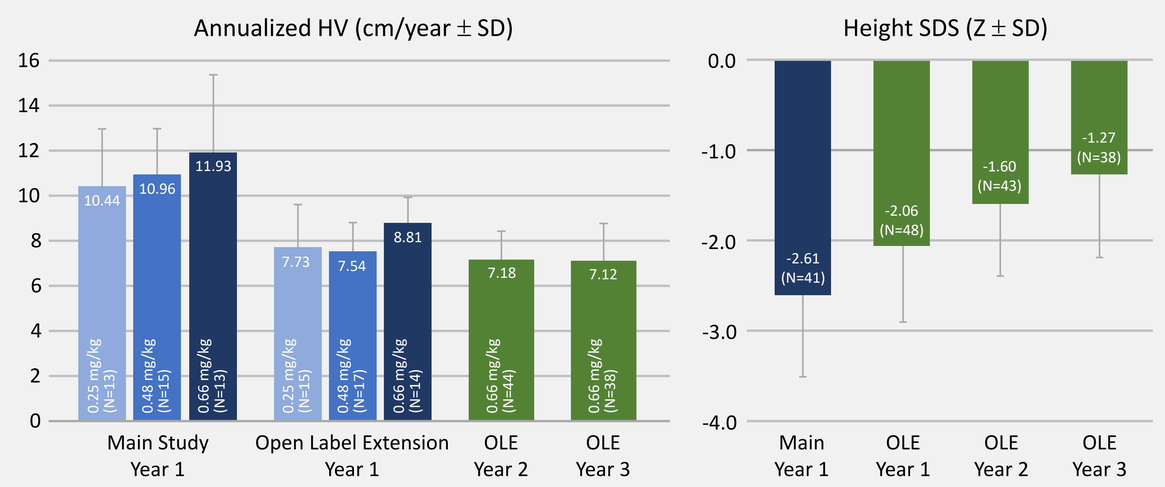
TEAEs > 5% of subjects	All (N=48)
Ear infection	4 (8.3)
Nasopharyngitis	4 (8.3)

Parameter, Mean (SD)		OLE Y1	OLE Y2	OLE Y3/Y4
HbA1c, %	N	45	43	40
	Mean	5.12 (0.282)	5.16 (0.309)	5.17 (0.343)
Fasting glucose, mmol/L	N	44	42	40
	Mean	4.65 (0.598)	4.45 (0.433)	4.68 (0.447)

Anti-Somatrogon antibody, n (%)	Overall (N=48)	OLE Y1 (N=48)	OLE Y2 (N=44)	OLE Y3 (N=43)
Anti-somatrogon Ab	17 (35.4)	12 (25.0)	11 (25.0)	11 (25.6)
Neutralizing Ab	0	0	0	0

- The safety and tolerability from the OLE study were comparable to that observed in the 12-month Phase 2 study [2] and the reported safety profile of daily r-hGH. Most AEs were of mild severity (75.8%) and no local tolerability issues were identified.
- There were 3 non-related serious AEs, and one probably related serious AEs of exacerbation of thoracic scoliosis that led to discontinuation.
- There were no changes in HbA1c, fasting glucose, or insulin over the 4 years of treatment in the OLE.
- Low titers of anti-somatrogon antibodies were detected in 17 subjects, of which 3 subjects had transient antibodies. All samples were negative for neutralizing Ab.

RESULTS: Efficacy



Parameter, Mean (SD)		OLE Y1	OLE Y2	OLE Y3
IGF-1 SDS, Z	N	43	41	38
	Mean	0.64 (0.956)	0.65 (1.082)	1.05 (0.819)

- Mean annualized HV over 3 years in the OLE shows that long-term somatrogon treatment resulted in sustained growth rate. Height SDS values showed height normalization over time.
- IGF-1 and IGF-binding protein-3 (IGFBP-3) levels remained within the normal range with ongoing somatrogon therapy.
- Subjects that had developed non-neutralizing Abs demonstrated similar annualized HV (cm/year) to subjects with no detectable Abs [8.43 (1.03) vs. 7.85 (1.66), 7.17 (1.31) vs. 7.19 (1.25), and 6.71 (1.19) vs. 7.36 (1.56)]; and height SDS [-2.31 (1.22) vs. -1.98 (0.70) , -1.71 (1.10) vs. -1.54 (0.63), and -1.47 (1.12) vs. -1.15 (0.80) for OLE year 1, 2, and 3, respectively].

CONCLUSION

- Somatrogon treatment demonstrated a favorable safety profile and local tolerability after four years of dosing in GHD pediatric subjects
- Serum IGF-1 SDS values were maintained within the normal range, and a growth rate comparable to that reported for daily hGH was observed
- Low titers of non-neutralizing Abs did not affect growth parameters and IGF-1 levels

REFERENCES

1. Calo D et al. Precis Med 2015, (2) e989: 1-8
2. Zelinska N et al. J. Clin. Endocrin. Metab. 2017, (102) 1578-1587