FORM 8-K

Current report filing

Filing Date: **2013-01-09** | Period of Report: **2013-01-08**
SEC Accession No. 0001193125-13-007690

FILER

Opko Health, Inc.
CIK:**944809**| IRS No.: **752402409** | State of Incorp.:**DE** | Fiscal Year End: **1231**
Type: **8-K** | Act: **34** | File No.: **001-33528** | Film No.: **13519579**
SIC: **2834** Pharmaceutical preparations

Mailing Address
4400 BISCAYNE BLVD.
SUITE 900
MIAMI FL 33137

Business Address
4400 BISCAYNE BLVD.
SUITE 900
MIAMI FL 33137
305-575-6015

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

Date of Report (Date of earliest event reported): January 8, 2013

OPKO Health, Inc.

(Exact Name of Registrant as Specified in 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

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))

Item 1.01 Entry Into a Material Definitive Agreement.

On January 8, 2013, OPKO Health, Inc., a Delaware corporation (the "Company") and OPKO IP Holdings, Inc. a limited company organized under the laws of Cayman Islands, an indirect wholly-owned subsidiary of the Company (the "Buyer"), entered into a share purchase agreement (the "Purchase Agreement") with Cytochroma Inc., a corporation organized under the laws of Ontario (the "Seller"), Cytochroma Holdings ULC, an unlimited liability company organized under the laws of Alberta ("Holdings"), Cytochroma Canada Inc., a corporation organized under the laws of Canada (together with Seller and Holdings, the "Seller Parties"), Cytochroma Development Inc., a corporation organized under the laws of Barbados ("Development"), Proventiv Therapeutics, LLC, a Delaware limited liability company ("Proventiv"), and Cytochroma Cayman Islands, Ltd., a limited company organized under the laws of Cayman Islands ("Cayman Newco").

Pursuant to the Purchase Agreement, the Buyer will purchase from the Seller the issued and outstanding equity securities of Cayman Newco and Proventiv for $100.0 million, which will be paid in shares of the Company' s common stock, par value $0.01 per share, (the "Common Stock") based on the volume-weighted average price per share of the Company' s Common Stock as reported on the New York Stock Exchange ("NYSE") for the ten trading days immediately preceding the date of the Purchase Agreement, or $4.874 per share (the "Stock Consideration"). In connection with the Purchase Agreement, the Company expects to issue 20,517,030 shares of the Company' s Common Stock to the Seller Parties at the closing.

In addition, the Purchase Agreement provides for the payment of up to an additional $190.0 million to the Seller Parties in cash or additional shares of the Company' s Common Stock, at the Buyer' s election, upon the achievement of certain milestones relating to development and annual revenue (the "Milestone Consideration"). If the Company elects to pay any portion of the Milestone Consideration in shares of the Company' s Common Stock, the amount of shares to be issued will be based on the volume-weighted average price per share of the Company' s Common Stock as reported on the NYSE or any other exchange system or market quotation system on which the Company is then listed for the ten trading days immediately preceding: (i) the milestone being achieved in the case of development milestones; or (ii) the earlier of the completion of the audit of the Company' s financial statements or the 105th day after the end of the applicable calendar year in the case of revenue milestones. In certain circumstances, the payment of the Milestone Consideration shall be made by the Company in cash, including if payment in shares of Company Common Stock would trigger an obligation to obtain the approval of the Company' s shareholders under applicable securities laws or NYSE regulations. In addition, the Company has the ability to off-set the payment of any Milestone Consideration by the amount of potential Company indemnity claims under the Purchase Agreement.

The Stock Consideration and any of the Milestone Consideration which the Company elects to pay in shares of the Company' s Common Stock will be issued in reliance upon an exemption from the registration requirements under the Securities Act of 1933, as amended (the "Securities Act"), pursuant to Section 4(2) thereof.

The Purchase Agreement contains customary representations, warranties, conditions to closing, indemnification rights and obligations of the parties. The transaction is expected to close during the first quarter of 2013.

Item 3.02 Unregistered Sales of Equity Securities.

The information required to be reported under this Item is incorporated by reference from Item 1.01 of this Current Report on Form 8-K.

Item 7.01 Regulation FD Disclosure.

On January 8, 2013, the Company issued a press release announcing that it entered into the Purchase Agreement. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

On January 8, 2013, the Company posted a presentation on its website (www.opko.com) regarding Cytochroma. A copy of the presentation is furnished as Exhibit 99.2.

The information contained in Item 7.01 to this Current Report on Form 8-K and Exhibits 99.1 and 99.2 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing by the Company under the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release of the Company, dated January 8, 2013
99.2	Seller Corporate Presentation January, 2013

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.

Date: January 9, 2013

By: /s/ Juan F. Rodriguez
Name: Juan F. Rodriguez
Title: Senior Vice President-
Chief Financial Officer

EXHIBIT INDEX

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Exhibit 99.1

OPKO HEALTH TO ACQUIRE TWO PHASE 3 PRODUCTS

New Vitamin D Prohormone and Phosphate Binder for Kidney Disease Patients

MIAMI−January 8, 2013 − OPKO Health, Inc. (NYSE:OPK) has entered into a definitive agreement to acquire Cytochroma Inc. (Markham, Canada) whose lead products, both in phase 3 clinical trials, are Replidea™ (coded CTAP101 Capsules), a vitamin D prohormone to treat secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency, and Alpharen™, a non-absorbed phosphate binder to treat hyperphosphatemia in dialysis patients.

Replidea™ has been shown in a phase 2b clinical trial to effectively and safely treat SHPT and the underlying vitamin D insufficiency in pre-dialysis patients. Vitamin D insufficiency arises in CKD due to the abnormal upregulation of CYP24, an enzyme which destroys vitamin D and its metabolites. Studies in CKD patients have demonstrated that currently available over-the-counter and prescription vitamin D products cannot reliably raise blood vitamin D prohormone levels or effectively treat SHPT.

“OPKO intends to market Replidea™ along with our proprietary point-of-care vitamin D diagnostic test currently in development,” stated Phillip Frost, MD, CEO and Chairman. “We envision these remarkable products as part of the foundation for a new and markedly improved standard of care for chronic kidney disease patients having SHPT and/or hyperphosphatemia.”

Alpharen™ has been shown safe and effective in treating hyperphosphatemia in the phase 2 and 3 clinical trials undertaken to date in dialysis patients. Hyperphosphatemia (elevated serum phosphorus) exacerbates SHPT and promotes bone disease, soft tissue mineralization and progression of kidney disease. Approximately 90% of dialysis patients in the United States require regular treatment.

Cytochroma’ s officers, including Charles W. Bishop, PhD, CEO, an authority on developing and commercializing successful new vitamin D therapies, and Eric J. Messner, MBA, having a noteworthy track record in pharmaceutical business development and in marketing and sales in the CKD arena, will join the OPKO management team. Prior to Cytochroma, Dr. Bishop and Mr. Messner held key positions at Bone Care International, Inc., a leader in vitamin D therapeutics acquired by Genzyme Corporation, now a division of Sanofi.

About Chronic Kidney Disease

CKD is a condition characterized by a progressive decline in kidney function. The kidney is normally responsible for excreting waste and excess water from the body, and for regulating various hormones. CKD is classified in five different stages – mild (stage 1) to severe (stage 5) disease – as measured by the kidney’ s glomerular filtration rate. According to the National Kidney Foundation, CKD afflicts over 26 million people in the US, including more than eight million patients with stage 3 and 4 CKD. In stage 5, kidney function is minimal to absent and patients require regular dialysis or a kidney transplant for survival.

About Vitamin D Insufficiency

Vitamin D insufficiency is a condition in which blood levels of vitamin D prohormones, collectively known as 25-hydroxyvitamin D, are inadequate. An estimated 70-90% of CKD patients have vitamin D insufficiency which can lead to SHPT and its debilitating consequences.

About Secondary Hyperparathyroidism (SHPT)

SHPT is a condition commonly associated with CKD in which the parathyroid glands secrete excessive amounts of parathyroid hormone (PTH). SHPT arises as a result of vitamin D insufficiency or impaired kidney function. Prolonged elevation of blood PTH causes excessive calcium and phosphorus to be released from bone, leading to elevated serum calcium and phosphorus levels, softening of the bones (osteomalacia) and calcification of vascular and renal tissues. SHPT affects 40-60% of patients with stage 3 and 4 CKD and approximately 90% of patients with stage 5.

About Hyperphosphatemia

Hyperphosphatemia, or elevated serum phosphorus, is common in dialysis patients and tightly linked to the progression of SHPT. The kidneys provide the primary route of excretion for excess phosphorus absorbed from ingested food. As kidney function worsens, serum phosphorus levels increase and directly stimulate PTH secretion. Stage 5 CKD patients must reduce their dietary phosphate intake and usually require regular treatment with phosphate binding agents to lower serum phosphorus to meet the recommendations of the National Kidney Foundation' s Clinical Practice Guidelines that serum phosphorus levels should be maintained at <5.5 mg/dL.

About OPKO Health, Inc.

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry leading positions in large, rapidly growing markets by leveraging its discovery, development and commercialization expertise and novel and proprietary technologies.

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding the benefits and synergies resulting from the acquisition of Cytochroma, including whether the Phase 3 clinical trials for Replidea™ and Alpharen™ may be completed on a timely basis or at all, that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results, that any of Replidea™, Alpharen™ and/or any of our compounds or diagnostics under development, including our point-of-care vitamin D diagnostic test may fail, may not achieve the expected results or effectiveness and may not generate data that would support the approval or marketing of products for the indications being studied or for other indications, that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than Cytochroma' s products for the indications being studied, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our filings with the Securities and Exchange Commission, that the various conditions to the closing of the transaction with Cytochroma may not be met, as well as risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and

competitive products and treatments. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

Contacts:

Steven D. Rubin or Juan F. Rodriguez 305-575-4100

Exhibit 99.2

Forward-Looking Statements

Certain statements and information included in this presentation are ‘‘forward-looking statements’’ under the Private Securities Litigation Reform Act of 1995 (PSLRA), including expectations regarding (1) the market opportunity and growth potential of the CKD patient population, (2) how to reach Cytochroma’ s target physician audience, (3) new potential indications for the CTAP101 Capsules, (4) the commercial opportunity for the CTAP101 Capsules, (5) the Phase 3 and NDA timelines for CTAP 101 through 2015, (6) the pipeline for clinical programs for CKD patients and early stage pipeline products, and (7) the U.S. market opportunity for Cytochroma’ s product candidates generally. Many factors could cause actual activities or results to differ materially from the activities and results anticipated in these forward-looking statements. These factors include that the various conditions to the closing of the transaction between Opko and Cytochroma may not be met, as well as risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. In addition, these forward-looking statements may also be adversely affected by scientific developments relating to chronic kidney disease, general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors.

A clinical stage specialty pharmaceutical company focused on Chronic Kidney Disease

Company Overview

Mission:

To Improve People's Lives by Treating and Preventing Clinical Consequences of Vitamin D Insufficiency and Secondary Hyperparathyroidism

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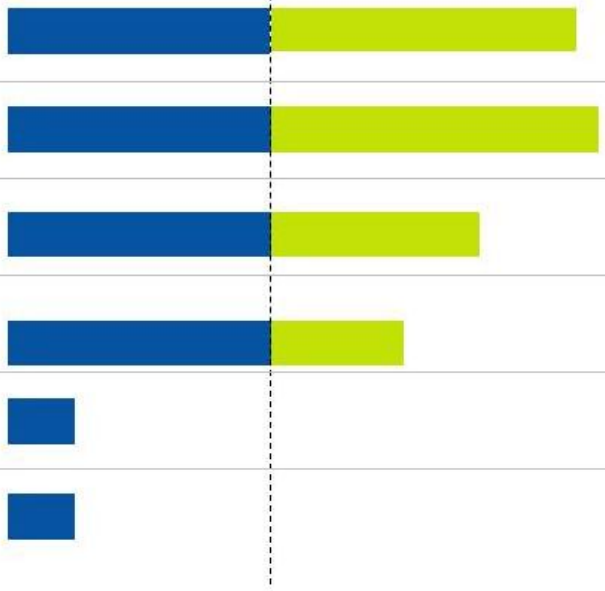
Cytochroma Product Pipeline

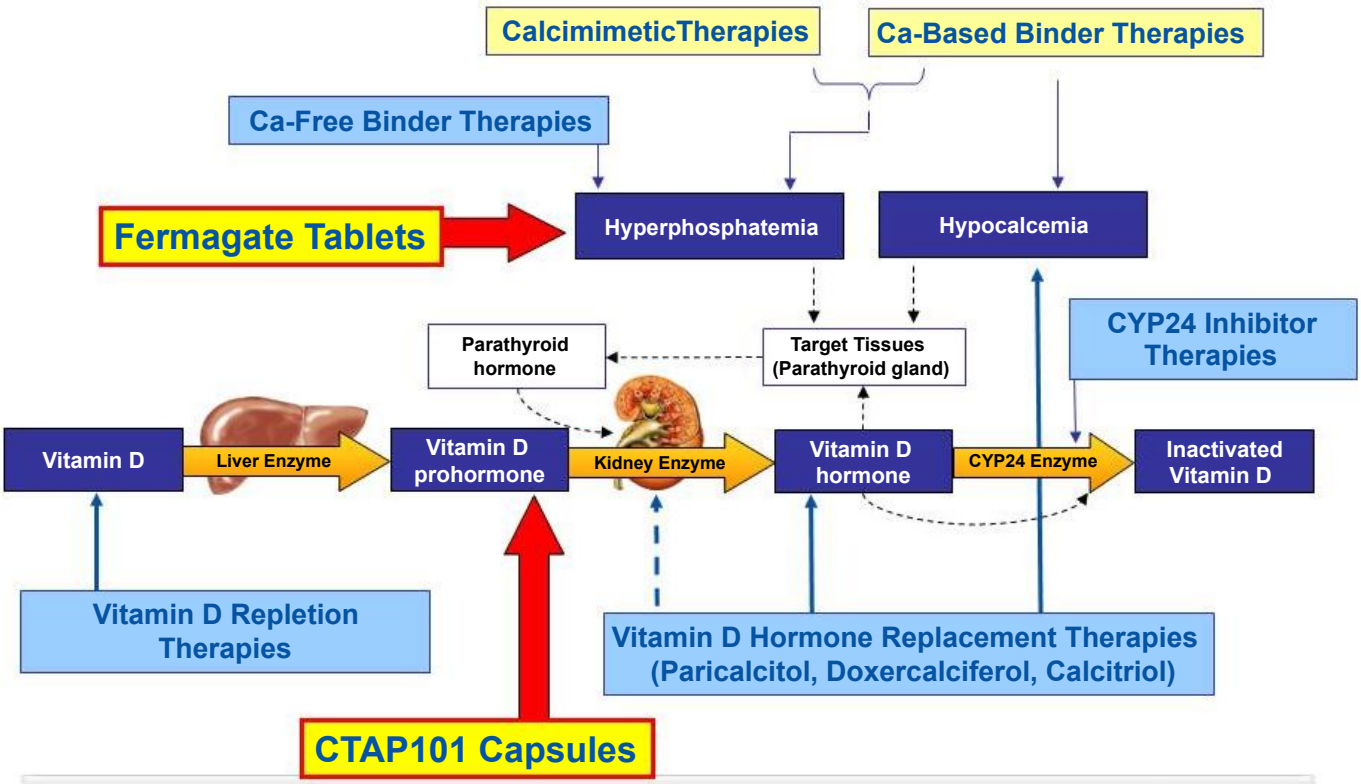
A clinical-stage specialty pharmaceutical company focused on CKD

Product	Indication	Territorial Rights
CTAP101 Capsules	Low 25D and SHPT* (CKD Stage 3-4 Patients)	Worldwide
Fermagate Tablets	Hyperphosphatemia (CKD Stage 5 Patients)	Worldwide
CTA018 Injection	Moderate to Severe SHPT* (CKD Stage 5 Patients)	Worldwide
CTAP201 Injection	Mild to Moderate SHPT* (CKD Stage 5 Patients)	Worldwide
Phosphate Transport Inhibitors	Hyperphosphatemia	Worldwide
CYP24 Inhibitors	CKD and pre-CKD	Worldwide



* SHPT = Secondary Hyperparathyroidism

Vitamin D: Central To SHPT Etiology & Treatment



Light blue boxes indicate Cytochroma's areas of focus

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Market Opportunity: Chronic Kidney Disease (U.S.)

The CKD patient population is large and growing as a result of cardiovascular disease, obesity and diabetes

- **Current U.S. sales are derived predominantly from Stage 5 CKD:**
  - Approximately $1.5 billion for SHPT therapies
  - Approximately $0.8 billion for hyperphosphatemia therapies
- **CKD Stage 3-4 patients represent a significantly greater, and largely untapped market opportunity**

			% of CKD Patients with:		
Stage	**Kidney Function**	**CKD Prevalence**	**Vitamin D Insufficiency (↓25D)**	**SHPT (↑ PTH)**	**Hyperphosphatemia (↑ Phosphorus)**
3	Moderate impairment	7.6 Million*	70%	56%	37%
4	Severe impairment	0.4 Million*	80%	60%	50%
5	Failure	0.5 Million**	90%	90%	70%

A 75-100 person specialty salesforce can readily reach Cytochroma's target physician audience:

- *Primary commercialization targets include 4,500-6,000 office-based nephrologists and 1,500-3,000 endocrinologists*
- *Other commercialization targets include geriatricians and 4,500 dialysis clinics*

*National Kidney Foundation 2002
**US Renal Data Service 2009 Annual Data Report
Sources: Levin, A et al., Kidney International 2007; 71: pp.31-38.
Gonzalez, E et al. Am J Nephrol 2004;24:503-510.
LaClair, R et al. Am J Kidney Dis 2005;45:1026-1033.

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CTAP101 Capsules

Product Overview

- Modified-release (MR) formulation of 25D*
- Safe and effective treatment for elevated PTH (SHPT) associated with low 25D levels in Stages 3-4 CKD
- Achieves more reliable increases in serum 25D and reductions in plasma PTH than nutritional vitamin D
- Lower risk of side effects compared to active 1,25D** products
- Preserves protective renal feedback mechanism
- Additional potential for new indications in:
  - Geriatric patients with low 25D levels and elevated PTH
  - Patients with GI or malabsorptive disorders
  - Osteoporosis
  - Organ transplant recipients

* 25-Hydroxyvitamin D3
** 1,25-Dihydroxyvitamin D

Clinical Status

- Phase 2b study complete and reported strong efficacy and safety data
- High proportion of patients achieved increase in 25D levels to target, as well as 30% reduction in PTH from baseline

Next Steps

- End of Phase 2 meeting with FDA in Q1 2012
- Phase 3 trials started in H2 2012 under SPA
- 505(b)(2) NDA filing in H1 2015

Intellectual Property

- Formulation and method of use patents pending
- CTAP101 US patent issued, protected through 2028

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Limitations of Existing Therapies

Company	Product	Use	Limitations
SANOFI	Ergocalciferol Capsules *(Drisdol)* Ergocalciferol Drops *(Drisdol)*	Nutritional Vitamin D: SHPT and Low 25D (Off-label)	▪ Limited systemic availability due to sequestering in fat tissue ▪ Inconsistent effects, dependant on GI functionality and bile production ▪ Limited efficacy to increase serum 25D levels and lower plasma PTH to K/DOQI* target levels
SANOFI	Doxercalciferol Capsules *(Hectorol)*	1,25D Hormones: SHPT only	▪ Cannot correct and may worsen low 25D levels ▪ Upregulate CYP24, which catabolizes both administered therapy as well as endogenous 25D and 1,25D ▪ Bypass protective renal feedback mechanism of downregulating CYP27B1 ▪ Cause aberrations in local and systemic calcium and phosphorus metabolism, leading to side effects such as hypercalcemia, hyperphosphatemia and soft tissue calcification
ABBOTT	Paricalcitol Capsules *(Zemplar)*		
Generic Manufacturers	Calcitriol Capsules *(Rocaltrol /Vectical)*		

CTAP101 consistently increases serum 25D and achieves meaningful reductions in plasma PTH without safety concerns

* K/DOQI - Kidney Disease Outcomes Quality Initiative is issued by the National Kidney Foundation and are practice guidelines for all stages of chronic kidney disease and related complications.

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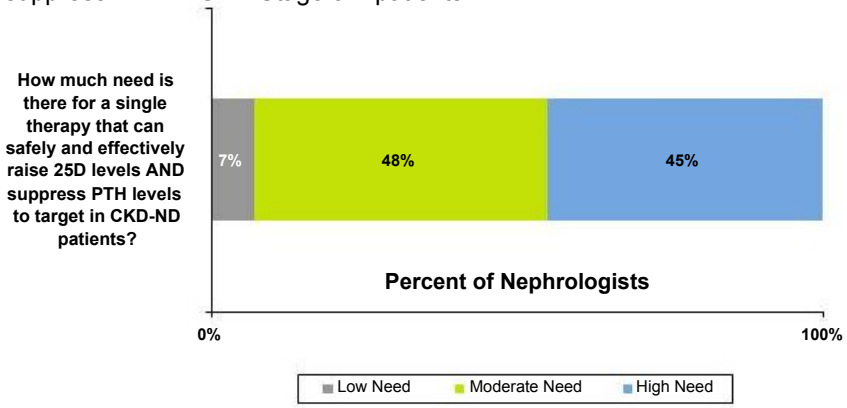
The Great Unmet Medical Need

Nephrologists report a significant need for a therapy that can raise serum 25D levels and suppress plasma PTH levels

- Nearly 60% of nephrologists frequently or always measure 25D levels in CKD Stage 3-4 patients
- Nearly 90% of nephrologists use nutritional vitamin D in CKD Stage 3-4 patients
- Over 90% of nephrologists agree that nutritional vitamin D has "limited efficacy to raise 25D and lower PTH"
- Over 90% of nephrologists agree that 1,25D hormones have "risks of side effects which limit dose and efficacy"
- Over 90% of nephrologists report a moderate-to-high need for a therapy that can safely and effectively raise 25D levels and suppress PTH in CKD Stage 3-4 patients



* As assessed through syndicated market research by BioTrends and proprietary research by Mattson Jack

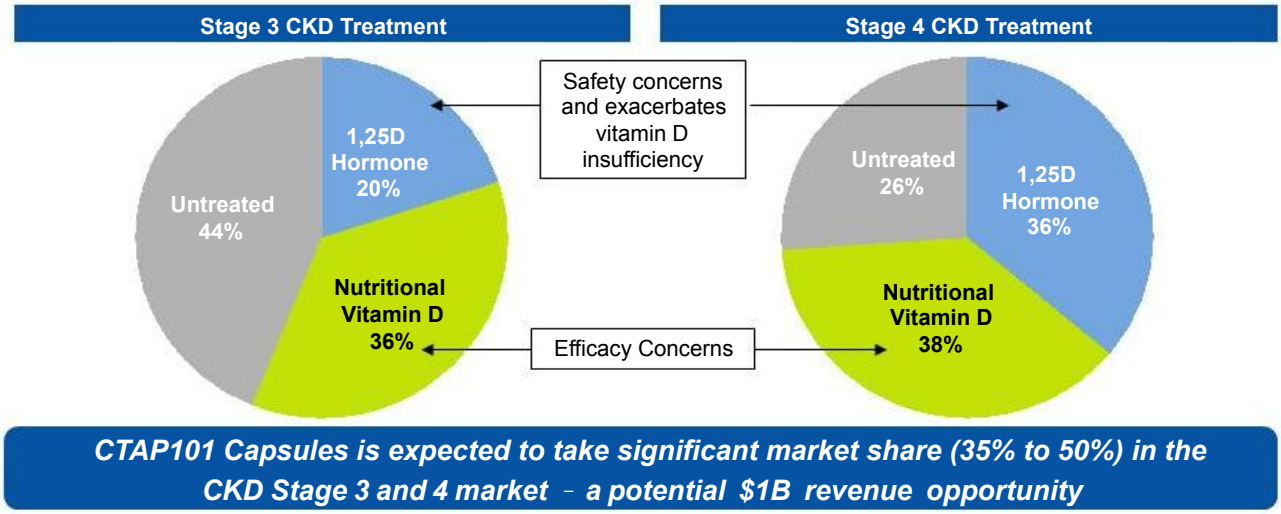
CTAP101: Significant Commercial Opportunity

- Low serum 25D and high plasma PTH are prevalent in CKD Stage 3-4 patients

  8.0M CKD Stage 3-4 patients in the U.S.

  - 4.0M patients with low serum 25D and high plasma PTH
    - ~1.0M patients seen by nephrologist
    - ~1.0M patients seen by endocrinologist

- Existing treatments are not effective or have significant safety issues
  - CTAP101' s efficacy and safety results compare favorably to both nutritional vitamin D and 1,25D hormones in CKD stage 3-4 patients and will drive untreated patients to start on CTAP101 Capsules



CTAP101 Capsules is expected to take significant market share (35% to 50%) in the CKD Stage 3 and 4 market – a potential $1B revenue opportunity

BioTrends Research Group, Inc. December 2010

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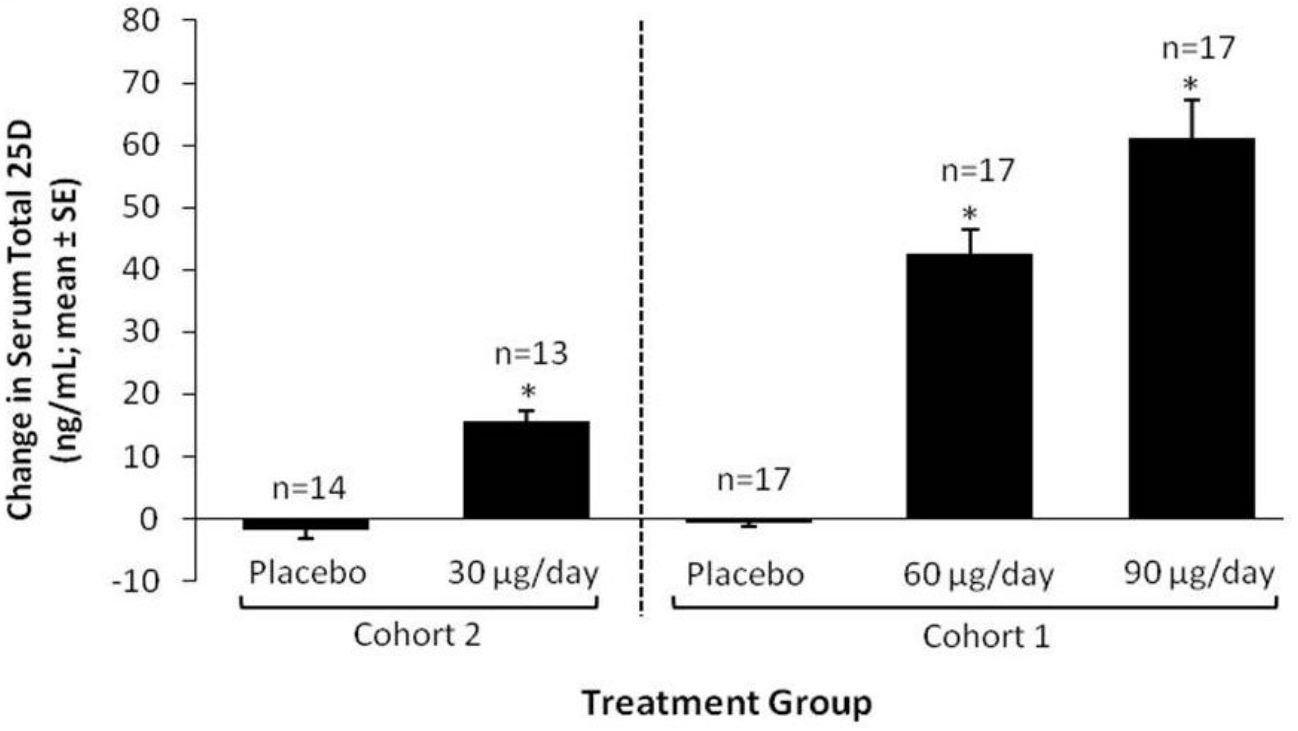
CTAP101: Corrects Vitamin D Insufficiency



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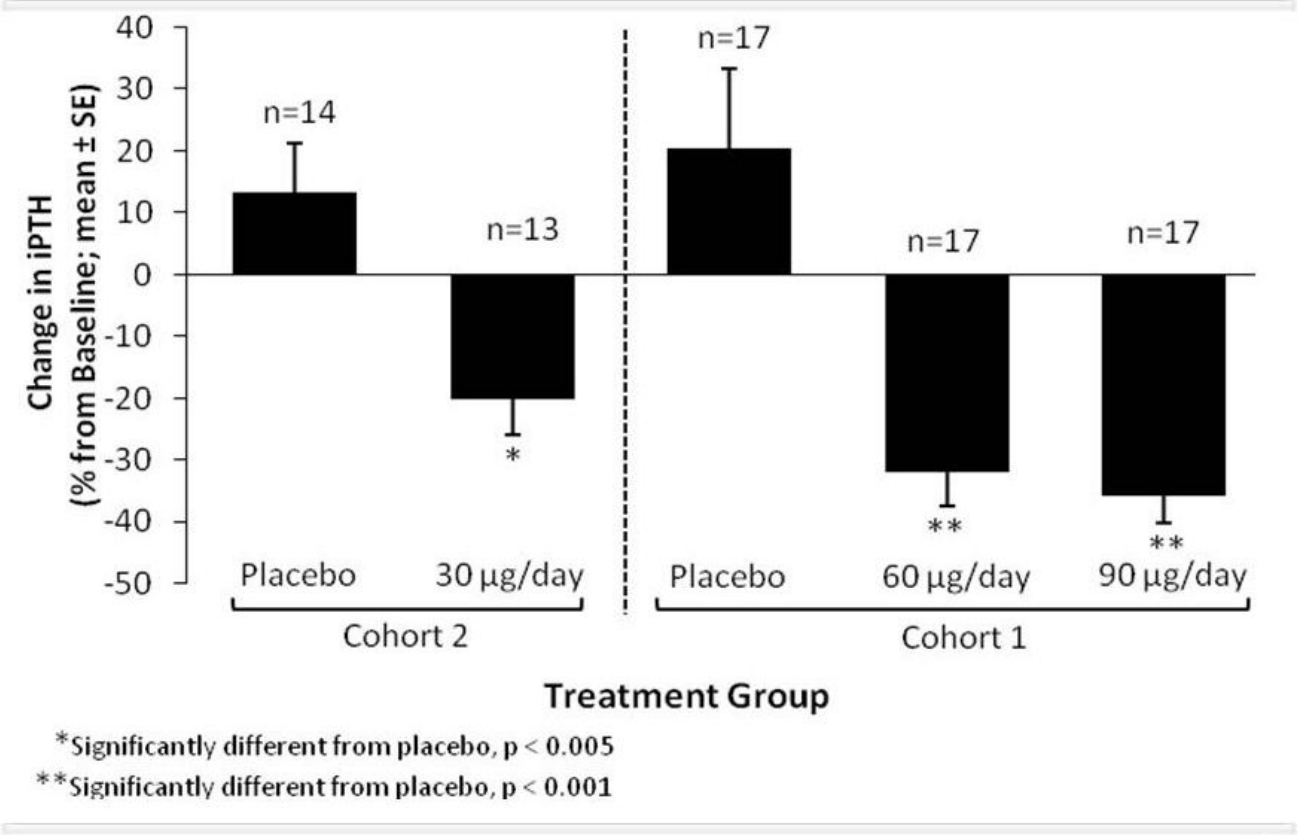
CTAP101: Corrects SHPT (Elevated Plasma iPTH)



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CTAP101 Capsules: Phase 2b Summary

Repeat dose proof of concept

- CTAP101 Capsules reliably increase serum 25D and reduce plasma PTH
- CTAP101 Capsules are safe in CKD Stage 3-4 patients
- CTAP101's efficacy and safety compare favorably to competing products
  - No competing products can consistently normalize 25D levels and produce significant reductions in PTH without safety concerns
  - The efficacy of OTC vitamin D at raising 25D or lowering PTH is modest; results are mixed and a relatively low percentage of patients respond
    - No clear dosing regimen for OTC vitamin D exists
  - 1,25D (calcitriol) doses that significantly reduce PTH (0.5 mcg/day) produce significant increases in serum calcium and cause hypercalcemia
    - Lower 1,25D doses (0.25 mcg/day) do not produce consistent, meaningful reductions in PTH
  - 1,25D analogues can significantly reduce PTH about the same amount as CTAP101 Capsules, but cause elevations in serum and urine calcium which raise safety concerns and limit their use

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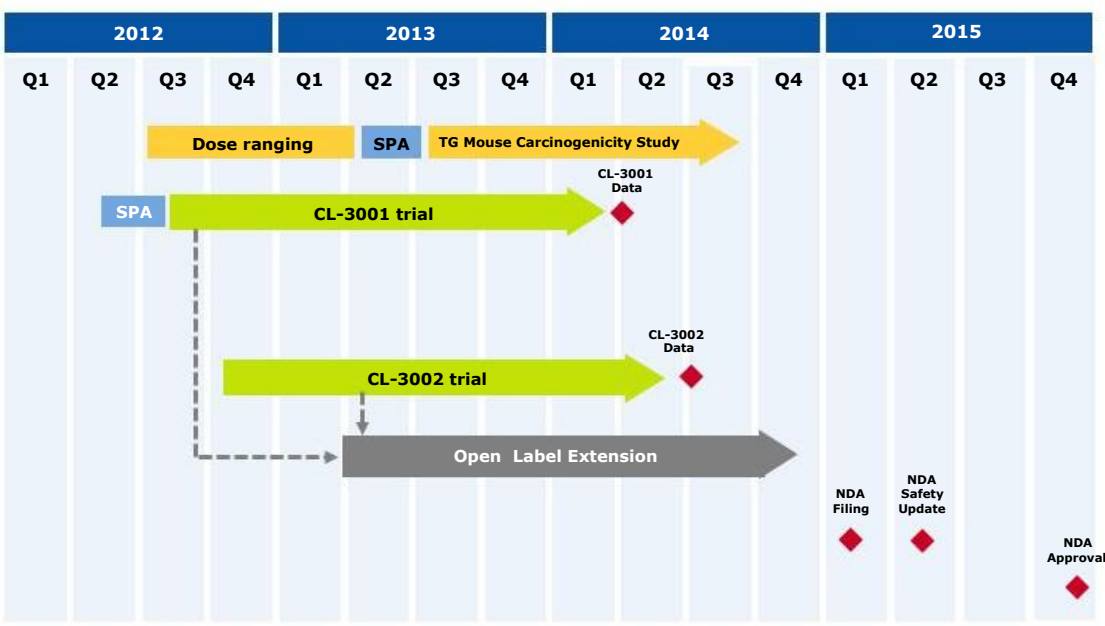
CTAP101: Phase 3 and NDA Timelines



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CTAP101-CL-3001 & CL-3002 Combined Site Map

= Selected investigator sites for study 3001 (33 Sites)

= Selected investigator sites for study 3002 (30 Sites)

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Corporate Highlights

CTAP101 Capsules is a Highly Differentiated Lead Asset

- First-in-class modified-release vitamin D prohormone that both corrects vitamin D insufficiency and controls SHPT* in patients with stage 3 or stage 4 CKD
  - ***No current therapy can reliably restore adequate serum 25D** and suppress elevated PTH****
- Compelling Phase 2b data in hand; Phase 3 program ongoing under SPA.
- USPTO recently issued a patent covering the product until '28
- NDA filing expected in 1H' 15

Broad and Deep Pipeline

- Two Phase 2 and two Phase 3 clinical programs, all for CKD patients
- Early stage pipeline includes new inhibitors of phosphate transport in the GI tract, as well as CYP24

Large Market Opportunity

- Cytochroma' s product candidates address $2.3 billion market in the U.S.
- Vitamin D insufficiency affects 70-80% of the 8 million CKD Stage 3-4 patients in the U.S.

* SHPT = Secondary hyperparathyroidism
** 25D = 25-hydroxyvitamin D
*** PTH = parathyroid hormone

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Promoting Health through Vitamin D Therapeutics

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Corporate Presentation
January 2013