
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): June 12, 2014

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

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33528
(Commission
File Number)

75-2402409
(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 (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))
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-

Item 5.07. Submission of Matters to a Vote of Security Holders.

On June 12, 2014, OPKO Health, Inc. (the “Company”) held its 2014 Annual Meeting of Stockholders (the “Annual Meeting”). Below is a summary of the proposals and corresponding votes.

1. All ten nominees were elected to the Board of Directors with each director receiving votes as follows:

Election of Directors	For	Withheld
Phillip Frost, M.D.	252,308,561	14,282,289
Jane H. Hsiao, Ph.D.	247,732,542	18,858,308
Steven D. Rubin	245,882,802	20,708,048
Robert A. Baron	263,825,181	2,765,669
Thomas E. Beier	255,927,907	10,662,943
Dmitry Kolosov	264,542,320	2,048,530
Richard A. Lerner, M.D.	264,415,310	2,175,540
John A. Paganelli	255,991,073	10,599,777
Richard C. Pfenniger, Jr.	264,345,443	2,245,407
Alice Lin-Tsing Yu, M.D., Ph.D.	246,350,609	20,240,241

2. The approval, on a non-binding advisory basis, of the compensation of the named executive officers of the Company (“Say On Pay”) as disclosed in the Company’s Proxy Statement for the 2014 Annual Meeting of Stockholders, pursuant to the compensation disclosure rules of the Securities and Exchange Commission, including the Compensation Discussion and Analysis, the compensation tables, and any related information found in the proxy statement. The votes on this proposal were as follows:

For	Against	Abstain
255,718,117	10,177,027	569,599

There were no broker non-votes for either proposal. No other matters were considered or voted upon at the Annual Meeting.

ITEM 7.01. Regulation FD Disclosure.

On June 12, 2014, the Company held its Annual Meeting of Stockholders. Copies of the Company’s Renal, Diagnostics, and API Division’s presentations presented at the Annual Meeting are furnished with this Current Report on Form 8-K as Exhibits 99.1, 99.2, and 99.3, respectively.

Statements made in the presentations which are not historical are forward-looking statements that reflect management’s current views with respect to future events and performance and may include statements concerning plans, objectives, goals, strategies, future events or performance, and underlying assumptions. Such statements are subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The fact that these presentation materials are being furnished should not be deemed an admission as to the materiality of any information contained in the materials.

The information contained in Item 7.01 to this Current Report on Form 8-K and Exhibits 99.1, 99.2, and 99.3 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, 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 Act, unless expressly stated otherwise.

ITEM 9.01. Financial Statements and Exhibits.*(d) Exhibits*

<u>Exhibit Number</u>	<u>Description</u>
99.1	Renal Division Presentation – 2014 Annual Meeting of Stockholders held June 12, 2014.
99.2	Diagnostics Division Presentation – 2014 Annual Meeting of Stockholders held June 12, 2014.
99.3	API Division Presentation – 2014 Annual Meeting of Stockholders held June 12, 2014.

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.

Date: June 17, 2014

OPKO Health, Inc.

By /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President,
Chief Financial Officer

EXHIBIT INDEX

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Update on Phase 3 Development
of
Rayaldee™ Capsules

June 12, 2014

Cautionary Statement

This presentation 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," "potential" and other words of similar meaning, including statements regarding our estimated revenues and financial projections, our ability to achieve high levels of growth, the potential for our products under development, the potential of our next generation prostate markers to dramatically reduce biopsies and increase detection of cancer, our ability to develop, test and launch new products, the expected timing of the studies and trials relating to our products under development, the outcome of our clinical trials and validation studies and that such outcomes will support commercialization, the expected market penetration and size of the market for our products under development, including rolapitant, Rayaldee™ (CTAP-101), hGH-CTP, the 4Kscore™, and our point-of-care diagnostic products for Total-PSA, testosterone, and Vitamin D, the potential benefits of our products under development, including whether the 4Kscore™ will improve selection of candidates for prostate biopsy and result in more than \$1 billion in savings on reduced biopsies and associated hospitalization, our ability to successfully commercialize our product candidates such as rolapitant, the 4Kscore™, Rayaldee™ (CTAP-101) and hGH-CTP, as well as products for other markets such as urology, women's health, cardiology, oncology, iPTH, and infectious disease, whether we will be able to develop Rayaldee™ (CTAP-101) for additional indications and whether Rayaldee™ (CTAP-101) will take significant market share in Stage 3 and 4 CKD patients with SHPT, whether Rayaldee™ (CTAP-101) will raise serum total 25-hydroxyvitamin D (25D) more effectively than any over-the-counter (OTC) or prescription (Rx) product currently marketed without the risk of hypercalcemia, expectations regarding patent coverage, the expected timing for commencing, completing and obtaining results for our clinical trials, the timing for FDA response to our submissions, the timing for release of trial data and seeking and obtaining FDA and European regulatory approvals, the life span of our patents, and the timing of commercial launch of our product candidates, as well as other non-historical statements. These forward-looking statements are only predictions and reflect our views as of the date they were made, and we undertake no obligation to update such statements. Such statements are subject to many risks and uncertainties that could cause our activities or actual results to differ materially from the activities and results anticipated in forward-looking statements, including risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, general market factors, competitive product development, product availability, federal and state regulations and legislation, and integration issues arising from the transactions, delays associated with development of novel technologies, unexpected difficulties and delays in validating and testing product candidates, the regulatory process for new products and indications, manufacturing issues that may arise, the cost of funding lengthy research programs, the need for and availability of additional capital, the possibility of infringing a third party's patents or other intellectual property rights, the uncertainty of obtaining patents covering our products and processes and in successfully enforcing them against third parties, and the possibility of litigation, among other factors, including all of the risks identified under the heading Risk Factors in our Annual Report on Form 10-K and other filings with the Securities and Exchange Commission.

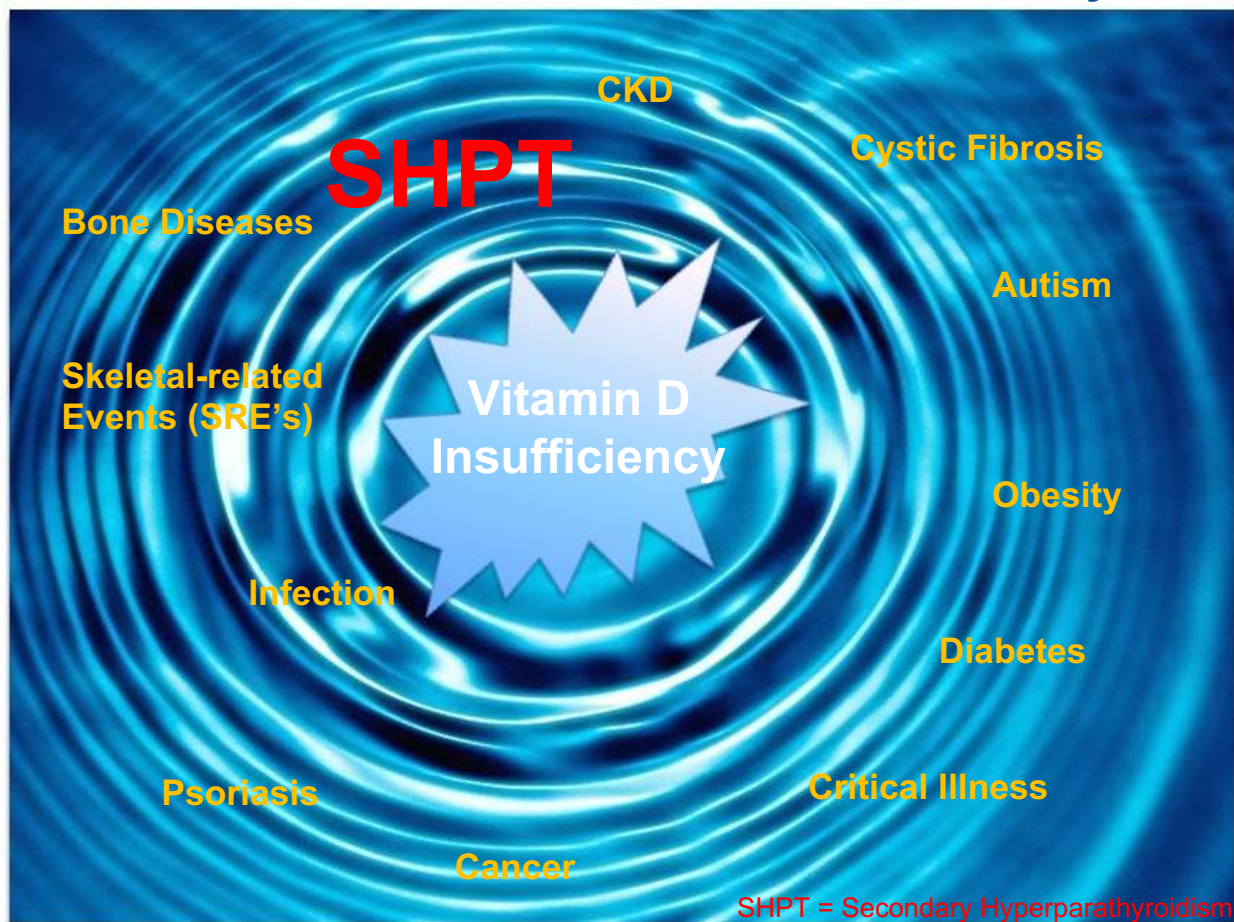
Mission Statement (for Renal Division)

Promoting Health through Vitamin D Therapeutics

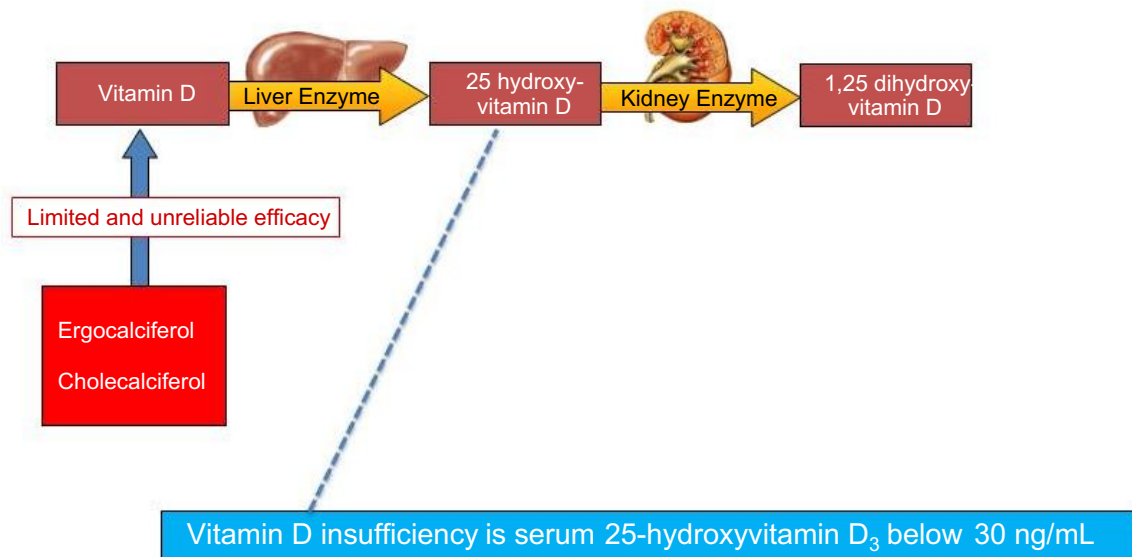


To Improve People's Lives by Treating and Preventing the Clinical Consequences of Vitamin D Insufficiency and Secondary Hyperparathyroidism

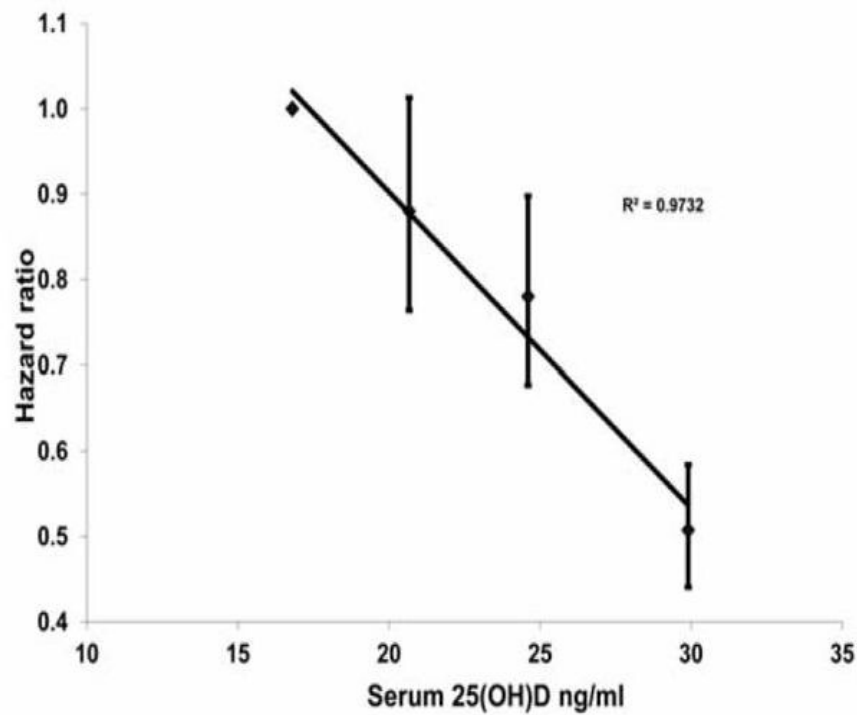
Diseases Associated with Vitamin D Insufficiency



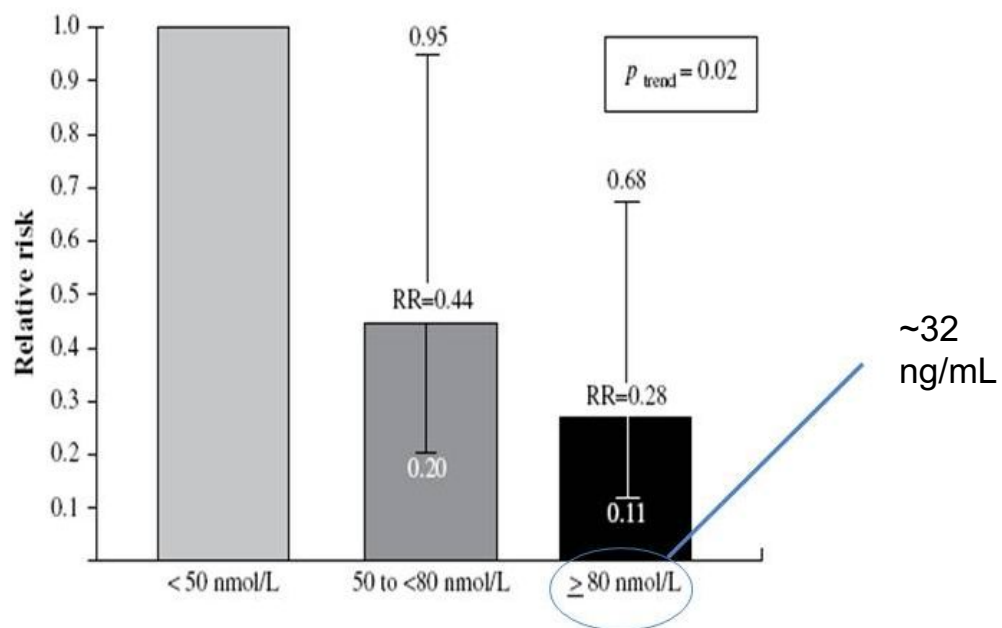
What is Vitamin D Insufficiency?



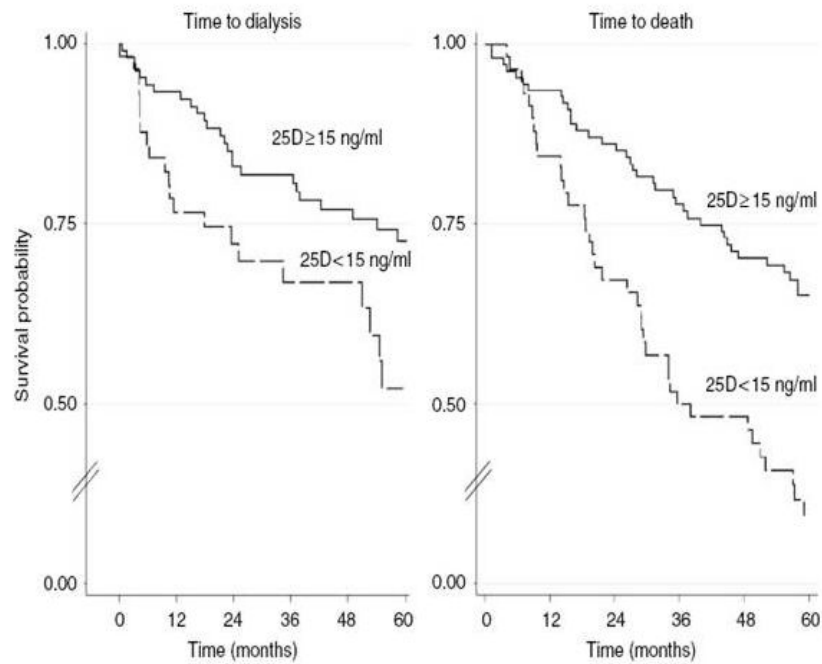
Vitamin D Insufficiency: Increases Mortality in Breast Cancer



Vitamin D Insufficiency: Increases Mortality in Colon Cancer



Vitamin D Insufficiency: Increases Mortality in CKD



Rayaldee (CTAP101) – A Late-Stage Investigational Drug

Product Overview

- Modified-release (MR) oral formulation of 25D₃* addresses significant unmet market need
- 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 including institutionalized elderly, osteoporosis & cancer.



Clinical Status

- SPA agreement with FDA in 3Q 2012
- Phase 3 trials initiated 3Q 2012
- Patient recruitment completed in 4Q 2013
- Clinical development guided by “all-star” Scientific Advisory Board
- NDA filing expected in 1H 2015

Intellectual Property

- Formulation and method of use patents allowed
- Rayaldee US patents issued, protected through 2028
- Additional global patents allowed or pending

* 25-Hydroxyvitamin D₃ or Calcifediol
** 1,25-Dihydroxyvitamin D or Calcitriol

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



















The CKD patient population is large and growing as a result of:

- Obesity
- Hypertension
- Diabetes

Stage	Kidney Function	CKD Prevalence	% of CKD Patients with:		
			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%

CKD Prevalence rates are similarly high outside of the U.S.,
and the population base is much larger.

Comparison of Vitamin D Therapies for Stage 3-4 CKD

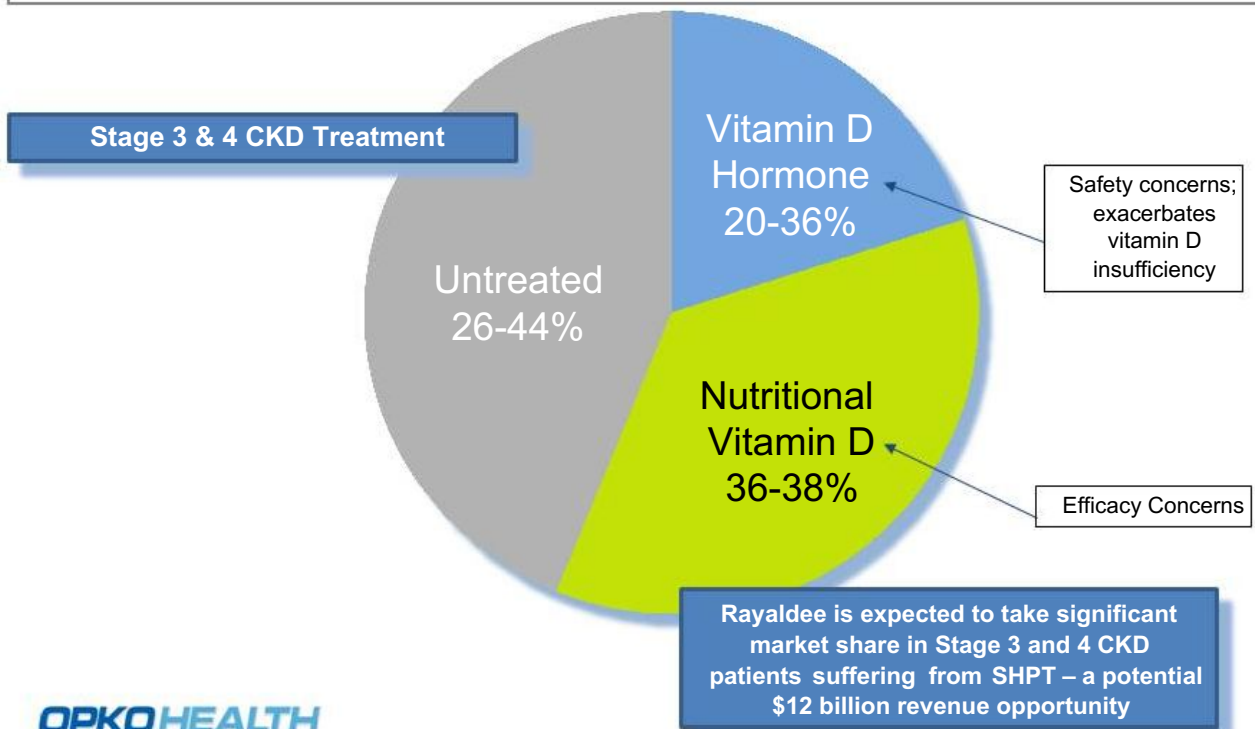
Drug	Active	Type	Effect on Blood Levels of:		
			25D**	Ca	iPTH
Rayaldee	Calcifediol (25-hydroxyvitaminD ₃)	Rx			
Vitamin D	Cholecalciferol/Ergocalciferol (vitaminD ₃ /vitamin D ₂)	OTC			
Drisdol™*	Ergocalciferol (vitaminD ₂)	Rx			
Rocaltrol™*	Calcitriol (1 α ,25-dihydroxyvitaminD ₃)	Rx			
Hectorol™	Doxercalciferol (1 α -hydroxyvitaminD ₂)	Rx			
Zemplar™*	Paricalcitol (19-nor-1 α ,25-dihydroxyvitaminD ₂)	Rx			

Rayaldee raises serum total 25-hydroxyvitamin D (25D) and lowers plasma iPTH more effectively than any over-the-counter (OTC) or prescription (Rx) product currently marketed without the risk of hypercalcemia.

Royaldee (CTAP101) - Commercial Opportunity

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

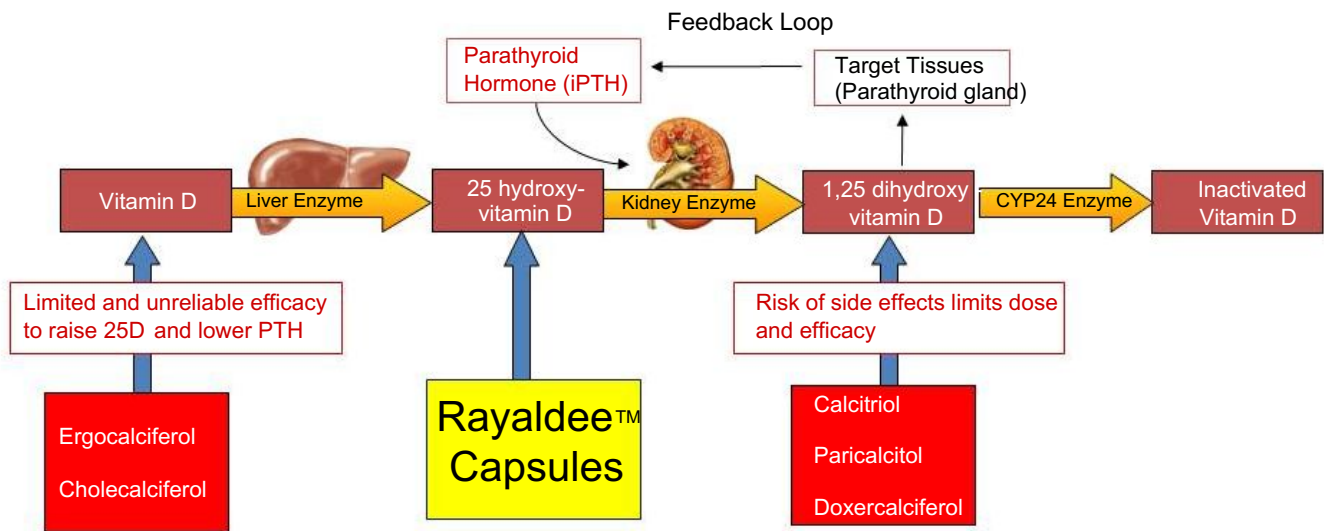
- 8 million CKD Stage 3-4 patients in the US
- 4 million patients with low serum 25D and high plasma PTH



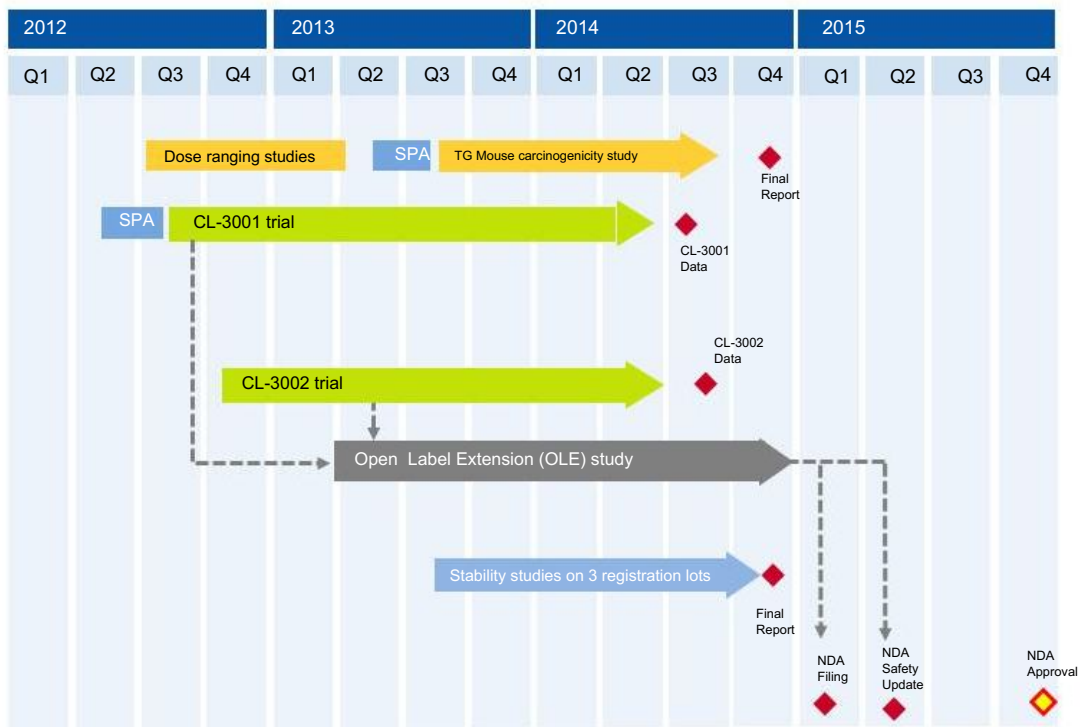
OPKO HEALTH
Renal Division

Source: BioTrends Research Group, Inc. December 2010

Royaldee Capsules: Positioning vs. Competitive Products



Rayaldee: Phase 3 and NDA Timelines



Publicly announced timelines:

- Top-line data from CL-3001 & CL-3002: mid-2014
- NDA filing: H1 2015

CL-3001 & CL-3002 Combined Site Map



📍 = Sites for CL-3001 (n=45)

📍 = Sites for CL-3002 (n=45)

Status Update: Phase 3 Trials *(as of June 5, 2014)*

CL-3001:

- 637 subjects entered screening
- 213 subjects were enrolled (~210 needed)
- Enrollment is 100% complete
- 109 subjects had stage 3 CKD (target = ~105)
- 104 subjects had stage 4 CKD (target = ~105)

CL-3002:

- 582 subjects entered screening
- 216 subjects were enrolled (~210 needed)
- Enrollment is 100% complete
- 113 subjects had stage 3 CKD (target = ~105)
- 103 subjects had stage 4 CKD (target = ~105)

CL-3003:

- 255 subjects have been enrolled
- Rollover failure rate from pivotal trials is 15.8% (budget = 20%)
- 91 subjects have completed the 6-month treatment period and exited

- 303 subjects have completed
- 62 subjects are still enrolled
- 64 premature terminations (15%)



Thanks!

OPKO
Diagnostics

Claros[®] 1

***Lab quality results in 10 minutes from
a finger-stick blood sample***

**1-3 day delay in lab
results, diagnosis,
and treatment**

**Maintenance of
certifications
and lab quality**

**Time and discomfort
for venous blood
draw**



COST



**PATIENT
CARE**

Real World Convenience

OPKO

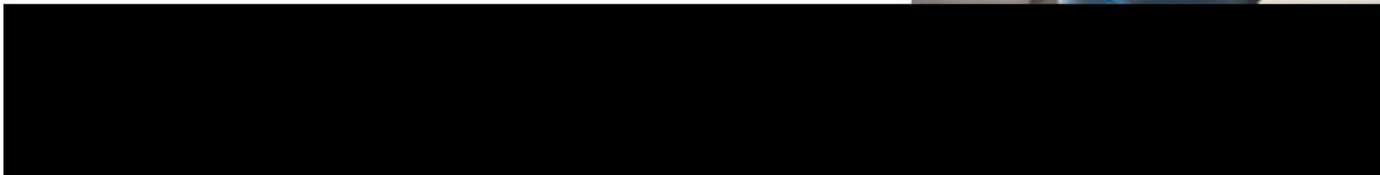


1-2

mins

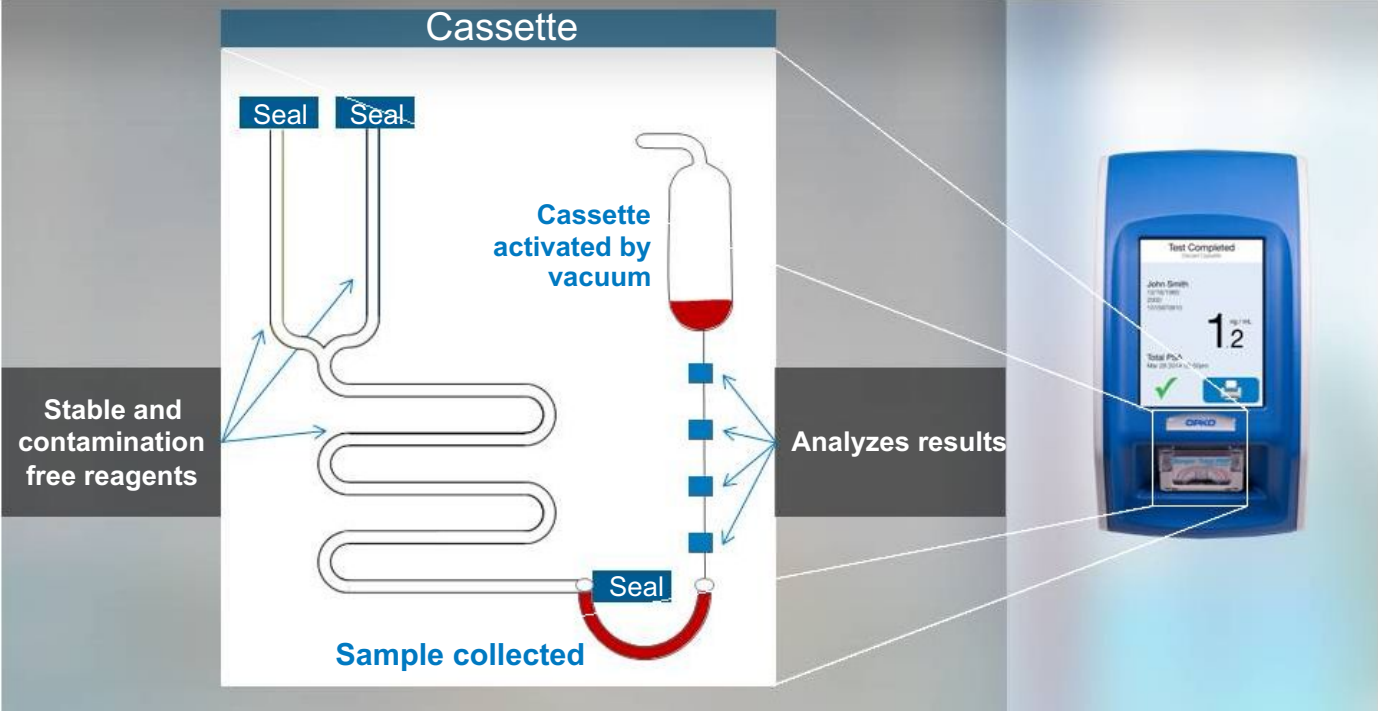
10

mins



Claros Microfluidic Assay Process

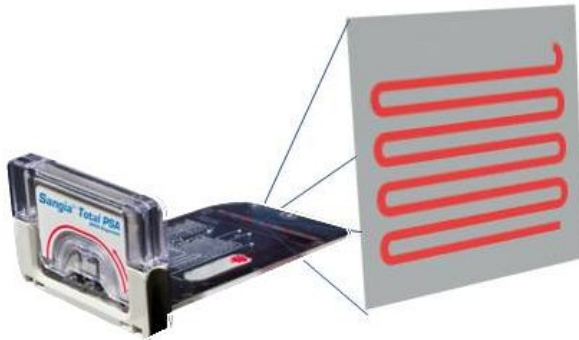
OPKO



Sangia™ Microfluidic Cassette

OPKO

Single, self-contained cartridge



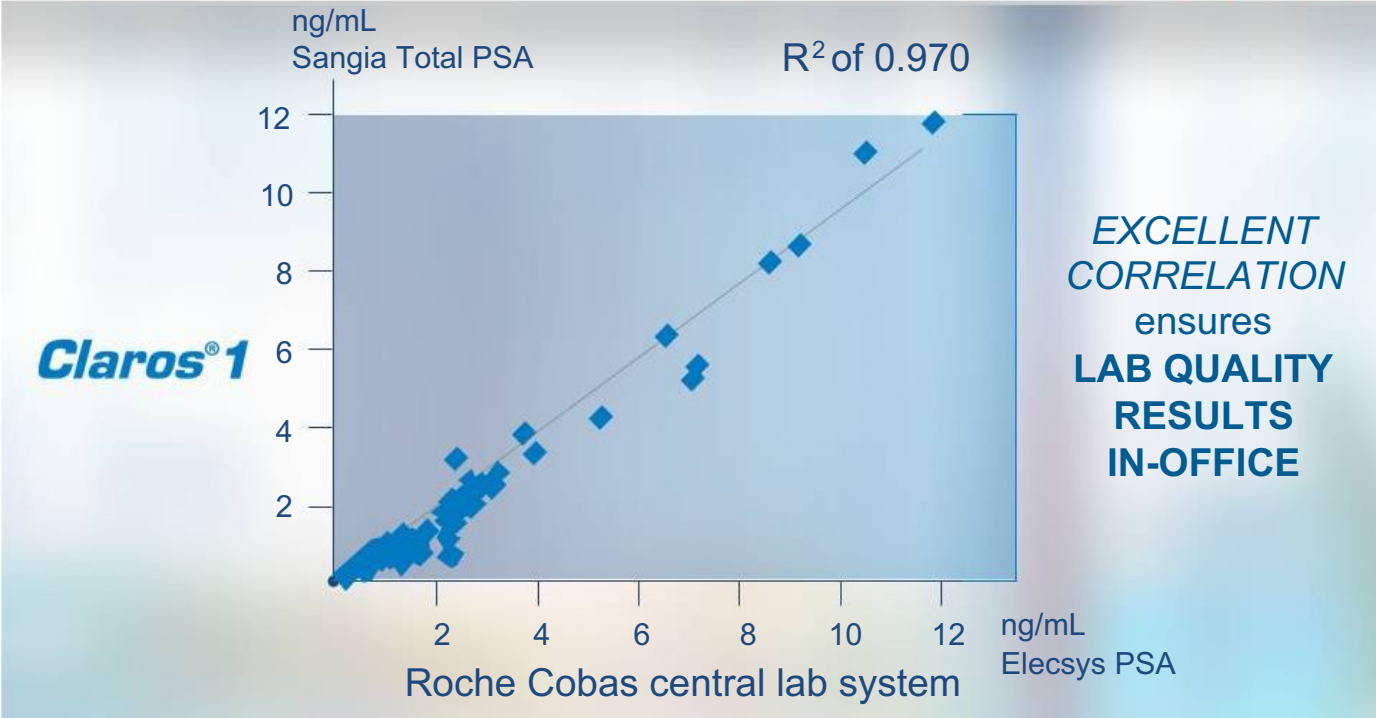
CONVENIENT



**LAB QUALITY
ACCURACY**

Proven Results

OPKO



Claros 1 Update

- Formulation of blood collector providing high reliability for results reporting
- SMA Chemistry providing rapid attachment and low LOQ
- Testosterone
 - FDA: Pre-submission comments received from FDA
 - On track to file 510(k) in 2014
 - CE Mark: 4Q2014
- PSA
 - FDA: Pre-submission response expected in August
 - Timing of 510k submission based on longitudinal trial requirements
 - CE Mark Update (Formulation and Chemistry): 4Q2014
- Vitamin D
 - On track to support launch of Rayaldee 1Q2016

OPKO
Diagnostics


4KscoreTM Test

***Personal risk for high-grade prostate cancer
...from a blood test***

The Issues of PSA Screening

OPKO





Prostate Cancer
is the 2nd leading
cause of cancer
death in men

29,000+

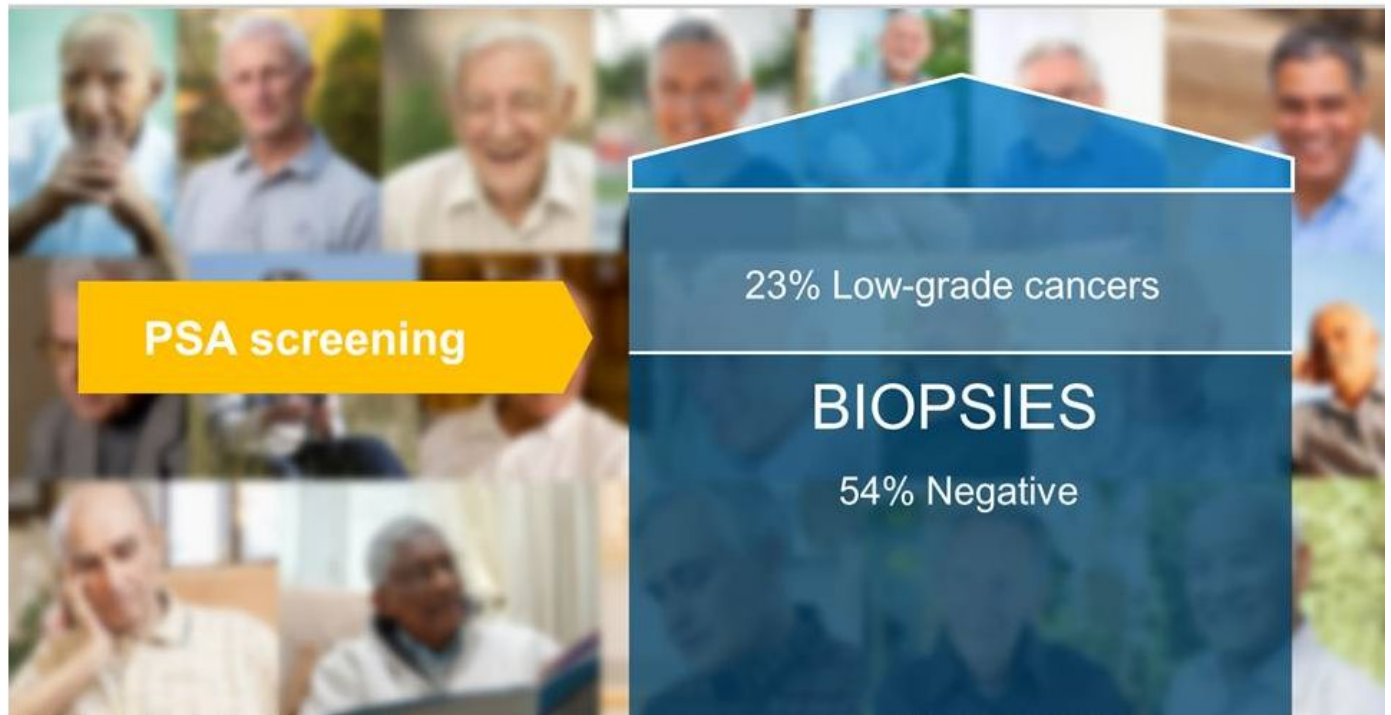
Projected deaths in the
US in 2014

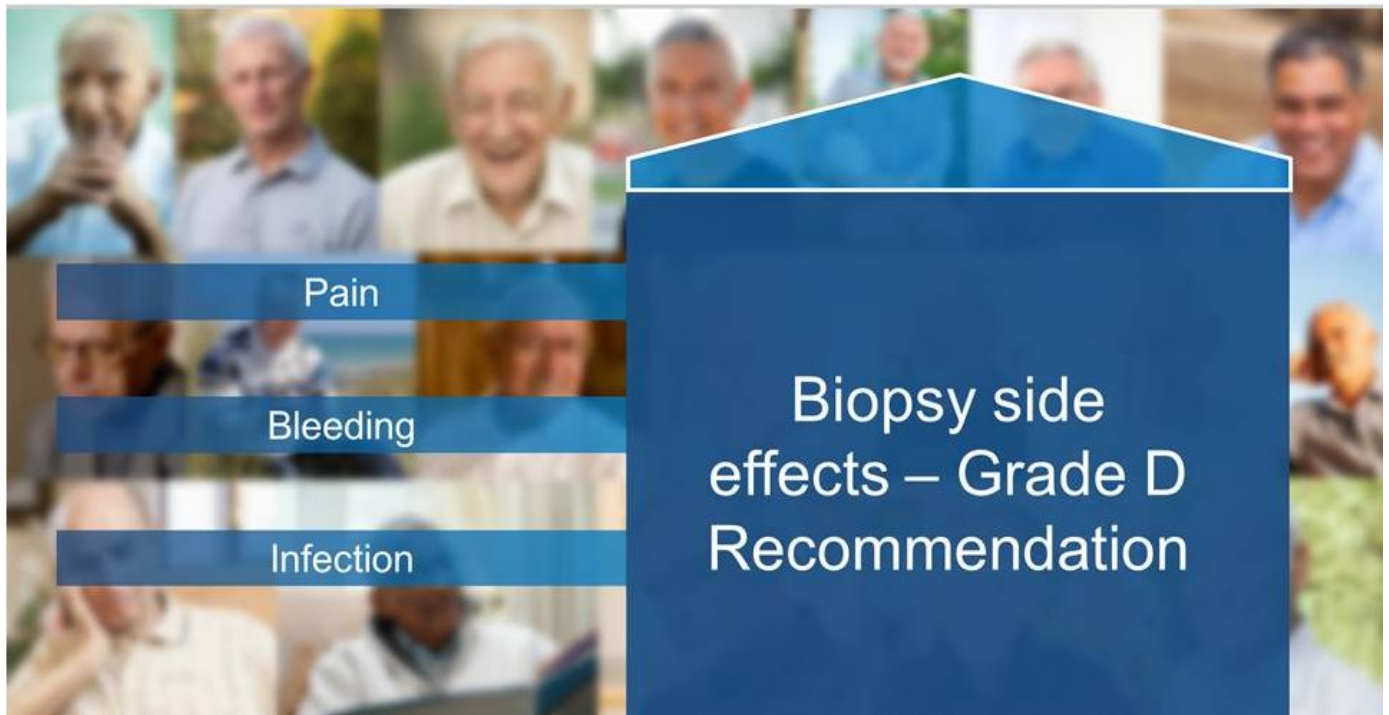
PSA screening

Decreased prostate
cancer mortality by
29%¹

1: Schröder FH, Hugosson J, Roobol MJ, Tammela TL, Ciatto S, Nelen V, Kwiatkowski M, Lujan M, Lilja H, Zappa M, Denis LJ, Recker F, Páez A, Mänttinen L, Bangma CH, Aus G, Carlsson S, Villers A, Rebillard X, van der Kwast T, Kujala PM, Blijenberg BG, Stenman UH, Huber A, Taari K, Hakama M, Moss SM, de Koning HJ, Auvinen A; ESRPC Investigators.

N Engl J Med. 2012 Mar 15;366(11):981-90. doi: 10.1056/NEJMoa1113135.





PSA SCREENING



Poor accuracy in distinguishing cancers

BIOPSY CANDIDATES



4Kscore™ Test

International team of researchers

Peter Scardino

(MSKCC, New York)

Andrew Vickers

(MSKCC, New York)

Hans Lilja

(MSKCC/Malmö/Oxford)

Timo Lövgren

(Univ. of Turku, Finland)

Kim Pettersson

(Univ. of Turku, Finland)

Jonas Hugosson

Sweden

Fritz Schröder

Netherlands

Monique Roobol

Netherlands

Caroline Savage

USA

Angel Cronin

USA

Mari Peltola

Finland

Charlotte Becker

Sweden

Sigrid Carlsson

USA/Sweden

Gunnar Aus

Sweden

Carl-Gustav Pihl

Sweden

Amine Benchikh

France

Alexandra Mashino

USA

Amit Gupta

USA

Arnaud Villers

France

Daniel Sjöberg

USA

Chris Bangma

Netherlands

Ewout Steyerberg

Netherlands

Theo van der Kwast

Netherlands

Over

10,000

men studied

9 cohorts in

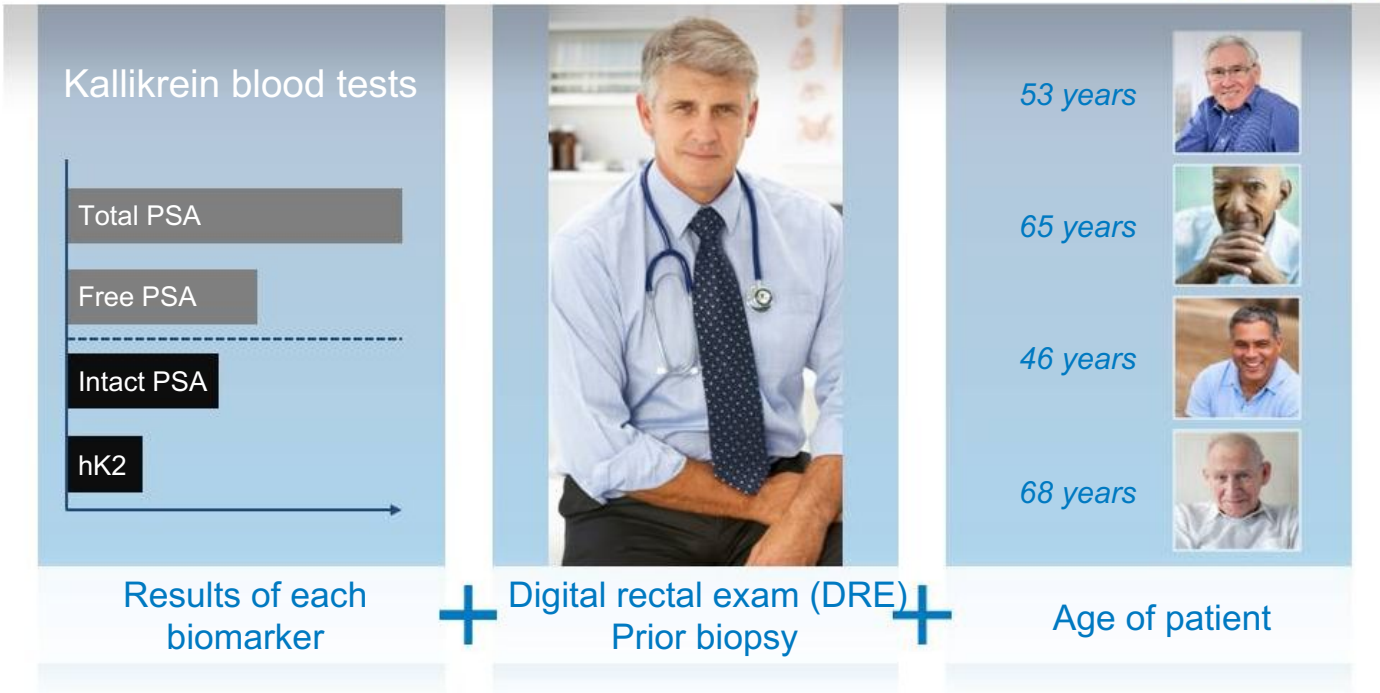
peer-reviewed
publications

3 decades of

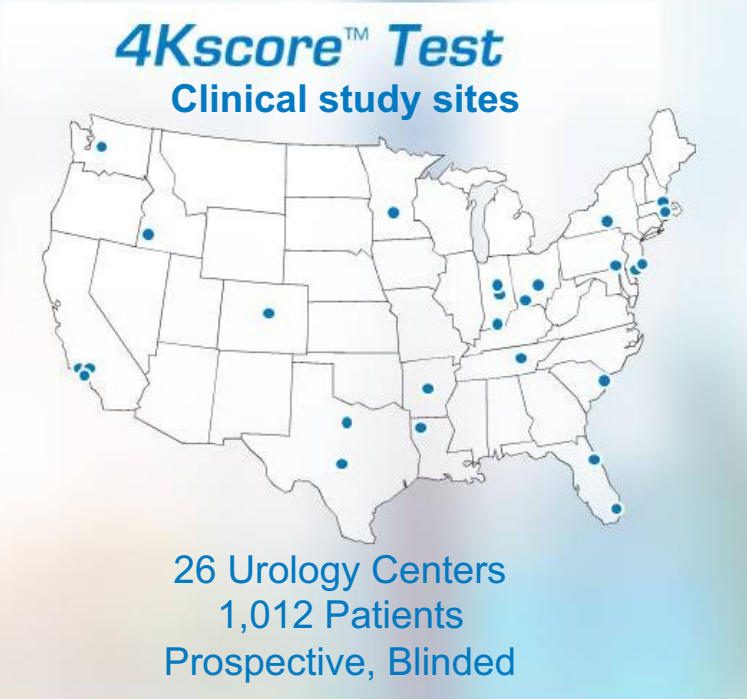
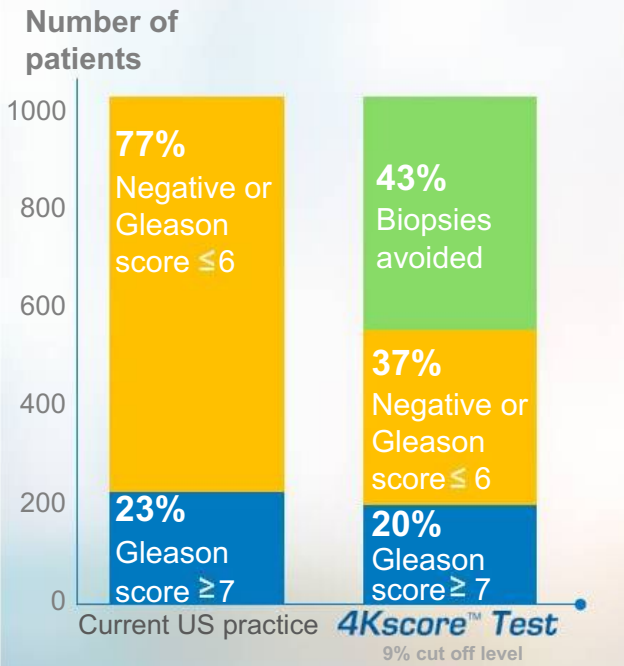
biomarker research

7 Elements of the 4Kscore Test

OPKO



Replication of Performance in a US Cohort



The advertisement features a blurred background of medical professionals in white coats. On the left, the text '4Kscore™ Test' is displayed in a bold, blue, italicized font. On the right, three blue rectangular boxes are stacked vertically, each containing white text. The top box says 'Accurate Probability for High-grade Cancer', the middle box says 'Decrease Unnecessary Biopsies', and the bottom box says 'Proven Results'.

4Kscore™ Test

Accurate Probability for
High-grade Cancer

Decrease Unnecessary Biopsies

Proven Results

4Kscore Test US Commercial Activities

- Post AUA follow-ups with LUGPA, PI Sites, etc.
- Test seeding program with select, regional urologists
- Launch web and social media platform
- Complete build out of a blood draw site network
- Publication of US Clinical Study (in preparation)
- Establish a US Speakers Bureau for local advisory board meetings
- Initiate Reimbursement process with private insurance, CMS

Welcome to FineTech Pharmaceutical



JUNE 12, 2014

- Manufactures high value, low volume specialty APIs and provides organic synthesis capabilities for OPKO's drug development projects
- Operates in a 35,000 sq. ft. state of the art, FDA approved facility with top of the line equipment
- Employs a highly motivated, experienced and creative team of 40 employees, mostly with Ph.D. or M.Sc. degrees
- Customers include leading generic pharmaceutical companies in the USA, Canada, Europe, Israel and South America
- Cost-efficient business with rapidly growing sales and very high margins

QUESTION:

What is the SECRET of this exceptionally high profitability?

JUNE 12, 2014

ANSWER:

PERFECT QUALITY MIX

- Facility/Equipment
- Science/Technology
- Ability to Create Intellectual Property
- Regulatory Affairs
- Effective Management of a Creative Team
- Commercial Acumen in choosing the right product at the right time

JUNE 12, 2014

This PERFECT QUALITY MIX enables a customer to be the first generic company to launch a specialty product with complex chemistry or patent challenges. In such cases companies are prepared to pay substantial premiums and commit to long-term agreements.

FineTech's Current Products

Cabergoline

Latanoprost

Nabilone

Travoprost

Bimatoprost

JUNE 12, 2014

Supporting OPKO's Drug Development Program

- ① SR-3306 – treatment of Parkinson disease
- ② C-34 – anti-tumor and immune-stimulating activity
- ③ Disaccharides – treatment of asthma
- ④ Different derivatives of vitamin D and CYP -24 inhibitors



JUNE 12, 2014



JUNE 12, 2014



JUNE 12, 2014



JUNE 12, 2014