
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 15, 2017

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)

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

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 (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))

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

On June 15, 2017, OPKO Health, Inc. (the “Company”) held its 2017 Annual Meeting of Stockholders (the “Annual Meeting”). Below is a summary of the proposal and corresponding vote.

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

Election of Directors	For	Withheld
Phillip Frost, M.D.	313,587,917	34,590,555
Jane H. Hsiao, Ph.D.	305,500,426	42,678,046
Steven D. Rubin	304,154,561	44,023,911
Richard M. Krasno, Ph.D.	344,682,759	3,495,713
Richard A. Lerner, M.D.	286,997,023	61,181,449
John A. Paganelli	291,162,570	57,015,902
Richard C. Pfenniger, Jr.	333,531,789	14,646,683
Alice Lin-Tsing Yu, M.D., Ph.D.	296,686,376	18,792,096

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 Annual Meeting. The votes on this proposal were as follows:

For	Against	Abstain
316,825,919	30,329,801	1,022,752

3. The selection of one year, on a non-binding advisory basis, as the frequency with which the stockholders are provided a non-binding advisory vote on Say on Pay in future years. The votes on this proposal were as follows:

1 Year	2 Years	3 Years	Abstain
309,086,990	692,622	37,254,593	1,144,267

Based on this result and in accordance with the previous recommendation of the Company’s Board of Directors, the Company will hold a non-binding, advisory vote on Say On Pay every year.

There were no broker non-votes for the proposals. No other matters were considered or voted upon at the meeting.

ITEM 7.01. Regulation FD Disclosure.

On June 15, 2017, the Company held its Annual Meeting of Stockholders. Copies of the presentations presented at the Annual Meeting are furnished with this Current Report on Form 8-K as Exhibit 99.1.

Statements are 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 Exhibit 99.1 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	OPKO Presentation – 2017 Annual Meeting of Stockholders held June 15, 2017.

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: June 15, 2017

By /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President,
Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	OPKO Presentation – 2017 Annual Meeting of Stockholders held June 15, 2017.



OPKO HEALTH, INC.

ANNUAL SHAREHOLDERS MEETING

JUNE 15, 2017



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, whether we will improve profitability and cash flow through revenue cycle management, our ability to reduce costs and improve profit margins by the end of 2017 and grow profit through 2018 in line with industry, the potential for our products under development, continued expansion in adoption rates and patient access for Rayaldee, expected growth in sales of Rayaldee and the 4Kscore test, the expansion of our renal field sales force and the timelines for doing so, expectations regarding the KDIGO guideline recommendations, expected milestones and royalties from the outlicense of our products, our ability to develop Rayaldee for additional indications, including stage 5 CKD, that the outcome of our clinical trials and validation studies will support marketing approval or commercialization for our products, the expected market penetration and size of the market for our products, the expected timing for commencing, completing and announcing results for our clinical trials, the timing for release of trial data and seeking and obtaining FDA and European regulatory approvals as well as reimbursement coverage for our products, our ability to obtain a positive coverage determination for the 4Kscore, and the timing of commercial launch of our product candidates. 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, the success of our collaboration with Pfizer and Vifor Fresenius, general market factors, competitive product development, product availability, federal and state regulations and legislation, 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.

RAYALDEE SENDS A CLEAR MESSAGE:

OPKO

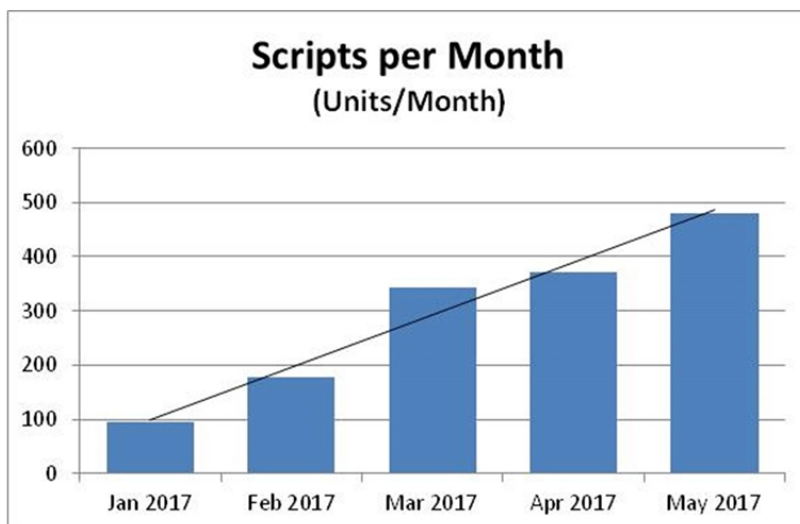


Rayaldee® signals changes in the treatment of SHPT

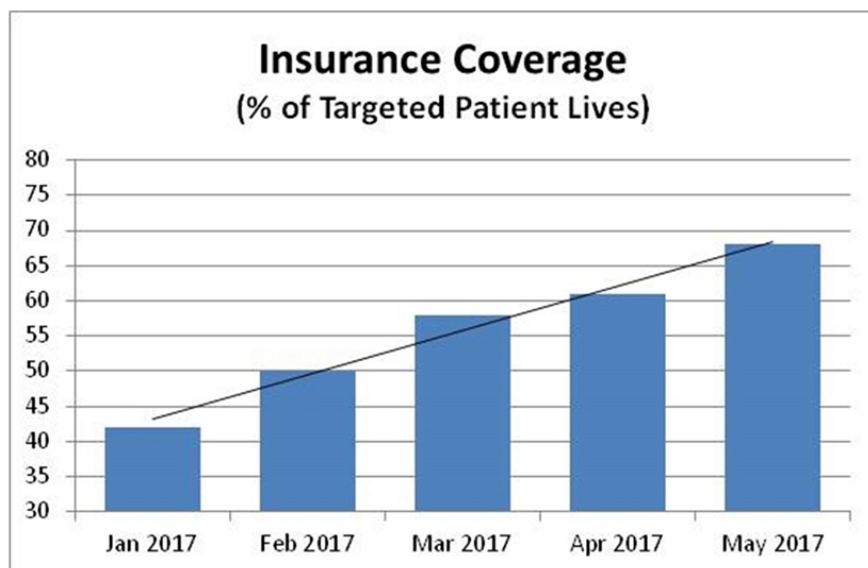
Rayaldee® is the first and only extended-release prohormone of the active form of vitamin D3 that brings 25-hydroxyvitamin D levels **up** and iPTH levels **down**, while keeps calcium and phosphorus levels **even**.

ADOPTION OF RAYALDEE IS STEADILY EXPANDING

OPKO



Source: IMS Data



- *Our **field sales force** at launch (35 Reps and 5 Regional Managers) was sized significantly smaller than most competitive field forces in nephrology.*
- *Our **field medical force** at launch (12 MSLs) was sized significantly smaller than most competitive medical forces in nephrology.*
- *Over the next 90 days, **we are planning to increase the size of the field sales force (to 70 Reps and 7 Regional Managers).***

- *Updated KDIGO guideline for CKD-Mineral and Bone Disorder is expected to be available online in June*, and published shortly afterwards in Kidney International.

Under the draft guideline:

- *Calcitriol and its 1 α -hydroxylated vitamin D analogs are not suggested for routine use* in adult patients with SHPT and CKD stages 3-4 (non-dialysis).
- *Nutritional vitamin D supplements (cholecalciferol or ergocalciferol) are characterized as “unproven”.*

RAYALDEE LICENSE WITH VIFOR FRESENIUS JOINT VENTURE



Terms of global collaboration with Vifor Fresenius Medical Care Renal Pharma (VFMCRP):

FINANCIAL

- Up to \$282 million in upfront and milestone payments to OPKO (\$50M to date)
- Up to \$555 million more if VFMCRP exercises option for U.S. dialysis market
- Double digit tiered royalties

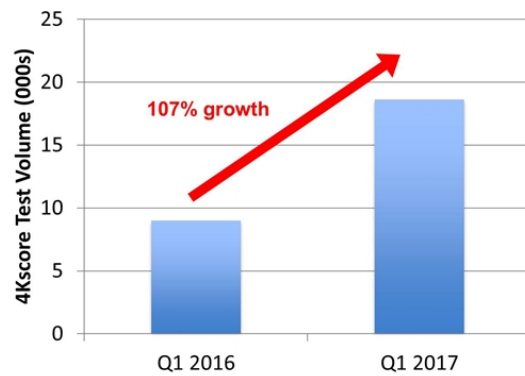
DEVELOPMENT

- OPKO and VFMCRP funding development program for hemodialysis indication
- VFMCRP responsible for funding:
 - All commercialization activities in the territory
 - All development costs necessary for approval in stage 3-4 CKD

COMMERCIAL

- VFMCRP has rights to commercialize RAYALDEE worldwide excluding OPKO's territory: U.S., Central and South America (except for Mexico), Russia, China, Taiwan, Japan

- New Drug Submission (NDS) filed in Canada in May 2017
- Phase 2 trial in hemodialysis patients targeted to start in Q4 2017
- Licensing efforts for other ex-US territories ongoing
- Marketing Authorization Application (MAA) in EU targeted for H1 2018



- Specialized sales force for Urology
- Sales incentive program
- TV advertisement in Northeast
- Expanded coverage



- Medicare and all large national payers providing good coverage
- Strong scientific and commercial presence at AUA (Boston, May 2017)
- VA clinical trial → VA formulary
- Study to address Palmetto LCD issue underway
- NCCN Guidelines update: positive for 4Kscore and Prostate Cancer Hereditary Panel testing

- PSA clinical trial data collection closing in early July
- PMA preparation underway
- Testosterone assay meets performance goals and in final stages of development
- 510(k) filing in 1Q2018



hGH-CTP PROGRAM STATUS



- **Initiated Phase 3 pediatric hGH-CTP study in December 2016**

- 220 patients, non-inferiority comparison of weekly hGH-CTP to daily growth hormone
- Global study CROs selected; sites initiated in December
- Easy-to-use, disposable, refrigerated pen device

- **Phase 3 adult hGH-CTP**

- Conducting post hoc outlier analysis
- No safety concerns
- Switching to pen device in open label extension

- **Initiating pediatric hGH-CTP registration study in Japan**

- 44 patients, comparison of weekly hGH-CTP to daily growth hormone
- Same pen device, dosage and formulation used in global study

PEN INJECTION DEVICE FOR GROWTH HORMONE

OPKO



OPK-88004 SELECTIVE ANDROGEN RECEPTOR MODULATOR (SARM) FOR THE TREATMENT OF BPH



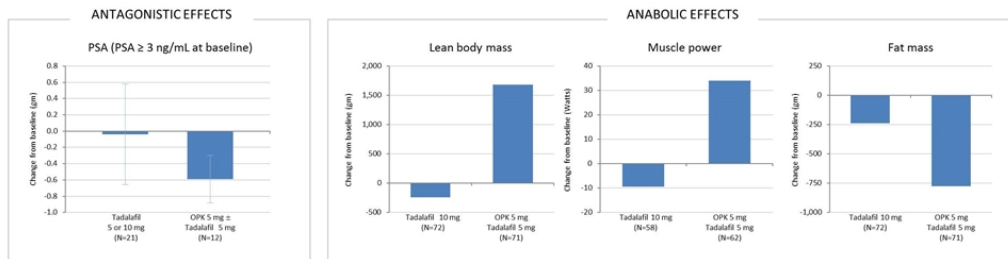
BENIGN PROSTATE HYPERPLASIA

- Enlarged prostate in men caused by changes in hormone balance and in cell growth
- > 50% of male over 70 years of age have BPH

MECHANISM OF ACTION

- OPK-88004, a selective androgen receptor modulator
 - Antagonistic effects on prostate
 - Anabolic effects on other tissues (i.e. muscle and bone)

OPK-88004 PHASE 2 STUDY IN 350 MALE SUBJECTS



OPK-88004 SELECTIVE ANDROGEN RECEPTOR MODULATOR (SARM) FOR THE TREATMENT OF BPH



OPK-88004 PHASE 2b CLINICAL STUDY (SAR 202)

- Once-a-day Dosing in Men with Signs and Symptoms of Benign Prostatic Hyperplasia
- 100 naïve BPH patients
- Expected to start in 2H 2017

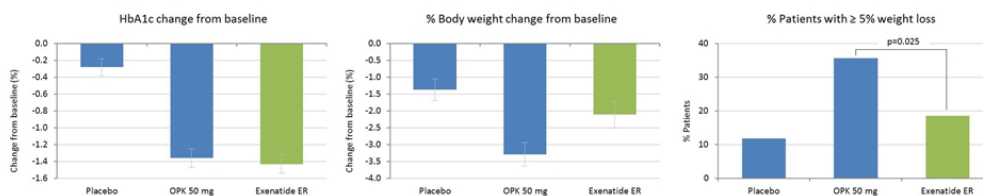
OPK-88004 -OTHER POTENTIAL INDICATIONS

- Urinary stress incontinence
 - Bladder leakage with physical activity
 - One in three women experiences stress incontinence in her life
- Frailty in dialysis patients
 - Frailty is common in dialysis patients of all ages and is a sensitive marker of morbidity and mortality
 - As high as 73% of hemodialysis patients may experience frailty and subsequent decrease in quality of life

OPK-88003 OXYNTOMODULIN ANALOG FOR THE TREATMENT OF TYPE 2 DIABETES AND OBESITY



- 26 million diabetics in US: drug development focused on: **blood glucose control** and **reducing body weight**
- OPK-88003 is an once-weekly analog with both GLP-1 and glucagon activity
- Data support that combining GLP-1 and glucagon activity provides superior weight loss
- Data from phase 2 study in 420 type 2 diabetes patients (week 12):



OPK-88003 CLINICAL DEVELOPMENT

- Phase 2b dose-escalation study expected to start by the end of the year
- Preparation of pen and formulation for phase 3 is ongoing

OPK-88002 NK 1 ANTAGONIST FOR THE TREATMENT OF PRURITUS IN DIALYSIS PATIENTS



PRURITUS

- Acute and chronic pruritus ("itching") occurs in 10% to 15% of the population
 - Most prevalent in skin, kidney and liver diseases
- Substance P is implicated in pruritus
- NK-1 antagonists block substance P activity and has been shown to reduce itching in human trials

PRURITUS IN DIALYSIS PATIENTS

- Major medical need and requires management
- 70 to 90% of patients Kidney dialysis patients suffer from Pruritus

PHASE 2a CLINICAL STUDY

- Expected to begin in 2H 2017

BioReference Laboratories

OPKO Shareholders Presentation

June 15th, 2017

The Vision...

We will be the premium provider of laboratory medicine and pathology consultation services and the definitive leader in diagnostic innovations.

The Focus...

Partner with healthcare providers, integrated health systems, payers, and patients to provide diagnostic information that preserves and prolongs health and more efficiently and effectively guides the precision treatment of disease.

The Metric...

We will be the laboratory that physicians, healthcare systems, *and* patients request for their testing and diagnosis.

Why?

It's the right thing to do.

The economic ecosystem is finally aligning with the right thing to do.

Tectonic Shifts In The Healthcare Ecosystem In Recent Years

- Consolidation and Integration
- Move from reimbursement by volume of care to risk-based, metric-driven "value" of care

The pace of transition is accelerating...

But we are still in transition.

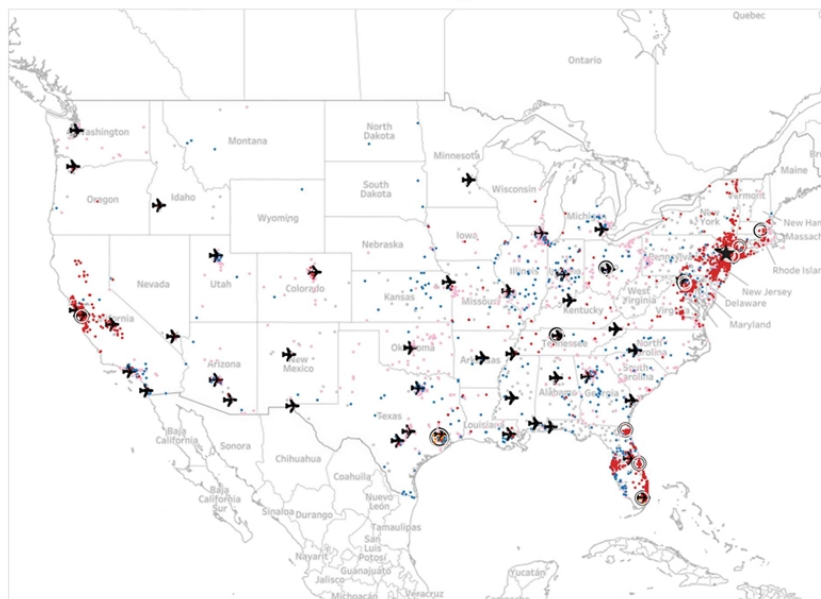
Company Highlights

- **Third largest clinical lab in USA**
- **Receives specimens from 40,000 patient per day**
- **Accounts in all 50 states**
- **300 Patient Service Centers and 600 In-Office Phlebotomists**
- **Central laboratory in Elmwood Park, NJ**
- **GeneDx laboratory in Gaithersburg, MD**
- **Satellite clinical laboratories:**
 - **Campbell, CA**
 - **Melbourne, FL**
 - **Tampa, FL**
 - **Houston, TX**



Click to highlight the Division, Airport, HQ, or Lab =>

- BRCA1
 - BRCA2
 - PTEN
 - APC
 - MLH1
 - MSH2
 - KRAS
 - TP53
 - NF1
 - NF2
 - CDKN2A
 - PTEN
 - APC
 - MLH1
 - MSH2
 - KRAS
 - TP53
 - NF1
 - NF2
 - CDKN2A
- Corrections
 - GenPath
 - LBS
 - Women's Health
 - ★ HQ
 - Lab
 - ✈ Airport



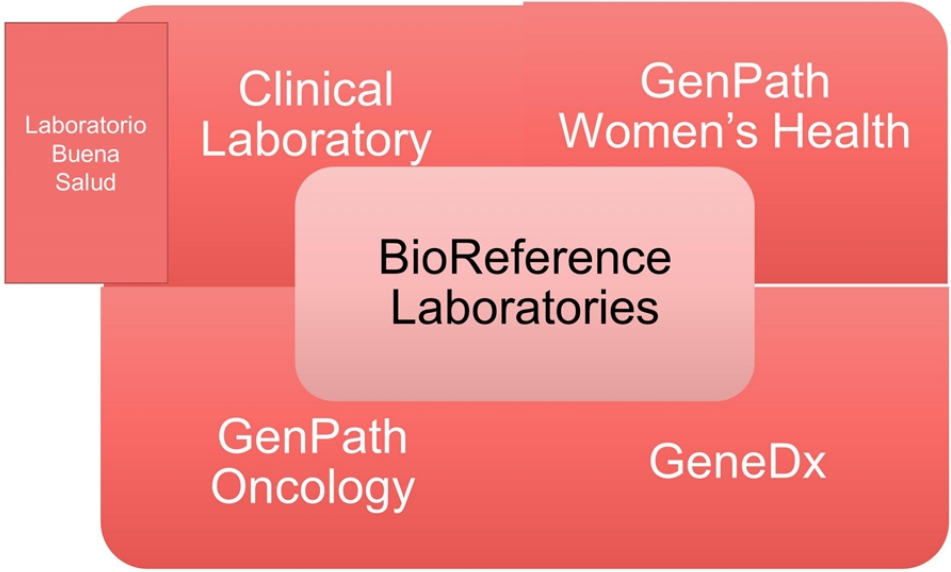
BioReference
LABORATORIES
an **OPKO** Health Company

Key Assets – BRLI

- Complete portfolio of testing from routine to esoteric
- 42 board-certified, subspecialty trained pathologists
- 30 years of patient data, highly diverse and longitudinal

Key Assets – GeneDx

- Premium brand in germline genomic testing – “the doctor’s doctor”
- Over 100 MD and PhD specialists in genomic medicine
- Over 100 Certified Genetic Counselors
- Largest portfolio of genomic tests in the country
- Leader in whole exome sequencing with largest patient database
- Proprietary software tools for bioinformatic analysis



BioReference Laboratories

Company Challenges and Solutions

BioReference
LABORATORIES
an **OPKO** Health Company

New Leadership To Execute On New Vision

- Dr. Ben Solomon - Director of GeneDx
- John Mooney - CIO
- Warren Erdmann - Chief of Staff and COO
- Jane Pine Wood - Chief Legal and Compliance Officer
- Victoria Laughman - Head of Sales for GeneDx

Aging Enterprise Systems

- Migration to Xifin billing system - 10/1/17
- Deployment of SAP for accounting and enterprise resource management - 10/1/17
- Deployment of Salesforce - In Progress

System and Process Overhaul

- Established Lean/Six Sigma Operational Excellence team
- Established Project Management Division
- Complete restructuring of IT Team, Systems, and Data Systems – In Progress

Divisional Challenges

Clinical Laboratory

- ❖ Value based payment systems
- ❖ Continued price compression
- ❖ PAMA

GenPath Women's Health

- ❖ Major changes in clinical guidelines for testing
- ❖ Pap Testing every 3 years

GenPath Oncology

- ❖ Consolidation of oncology practices into integrated healthcare systems
- ❖ Requires IT expertise to rapidly interface into enterprise systems

GeneDx

- ❖ Pricing pressures by top-line focused startups
- ❖ Increasing demand for ease of access

The Strategy - Collaborative Partnerships

Hospital Systems

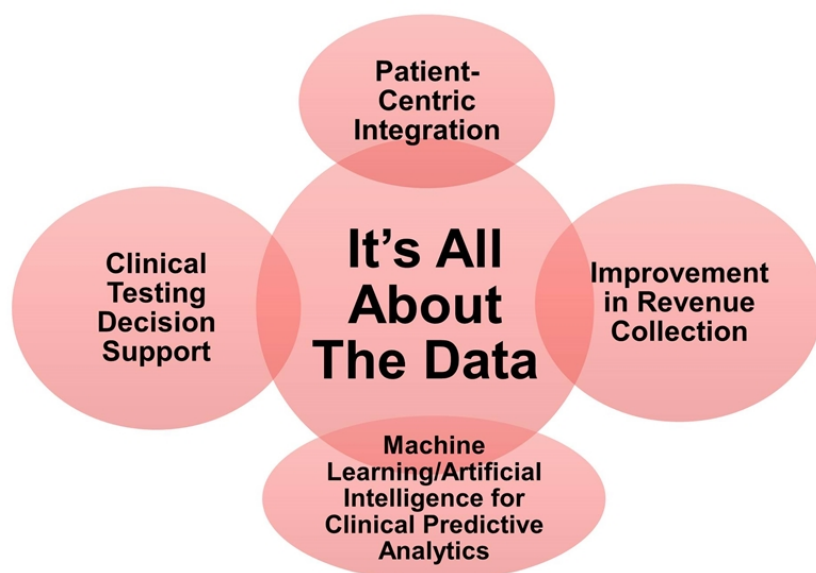
- Northwell Joint Venture
- University of California - Exclusive Contract
- Vanderbilt University
- Kaiser Permanente

4K Score

- Adoption by integrated healthcare systems
- Key Opinion Leader Support

Lead with GeneDx

- Opens the door to the remainder of the portfolio
- Growth by adoption of tests by owned and affiliated practices



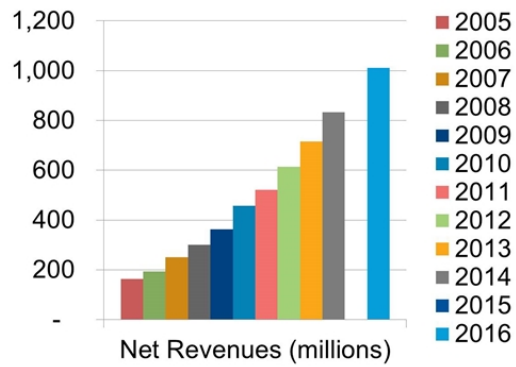
Profitability and cash flow

- Improve profitability and cash flow through a revenue cycle management program
- Focus on operational effectiveness to meaningfully reduce costs
- Target improved profit margins during 2017
- Grow profit in 2018 and beyond to be in line with the industry

Historical growth and profitability

(in 000's)

	Fiscal Year											
	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Net Revenues	163,896	193,134	250,431	301,071	362,654	458,024	522,081	614,255	715,354	832,282		1,010,442
Net Income	7,621	11,291	13,957	15,617	21,850	26,381	36,359	42,156	45,825	46,758		24,711



- As a result of the acquisition, 2015 is not comparable and therefore is not reflected in the table or chart.

Historical Cash Flows

(in 000's)

Period	Operating Cash Flows	Capital Expenditures	Free Cash Flows
2005	2,899	2,860	39
2006	5,200	2,859	2,341
2007	5,897	7,745	(1,848)
2008	18,876	7,824	11,052
2009	24,366	8,749	15,617
2010	13,405	16,494	(3,089)
2011	30,946	14,117	16,829
2012	53,098	15,715	37,383
2013	17,662	25,100	(7,438)
2014	16,575	15,523	1,052
2016	129,147	11,251	117,896

