

OPKO Health, Inc. (OPK - \$ 13.45)

Broadly Diversified and High Potential Medical Products Under One Roof

We are initiating coverage of OPKO Health with a Buy rating and 12-month price target of \$22. OPK is a diversified medical products company on the verge of revenue expansion from both diagnostic and pharmaceutical operations.

- **OPK is heading to a revenue expansion period.** The recent Bio-Reference Laboratories (BRL) acquisition brings additional revenue plus a large sales force to support OPKs 4Kscore test sales. Coupled with three drugs in OPK's pipeline (Rayaldee, Rolapitant and MOD-4023) that potentially could be approved and enter the market over the next 24 months; the company is in a transformative stage in our opinion. We estimate OPK could become cash positive starting 2016 with continued margin improvements going forward as product mix improves.
- **Three potential pharmaceutical product launches over next 2 years followed by a robust pipeline.** Should all receive positive reviews by the FDA, Rolapitant (in CINV) could enter the market in 4Q15; with Rayaldee (in SHPT) and MOD-4023 (in GHD) entering in 2H16 and 2H17, respectively. Rolapitant and MOD-4023 are partnered with Tesaro and Pfizer, respectively. Together, we estimate the total peak sales potential exceeds \$2.0+ billion.
- **Addition of Bio-Reference Laboratories coupled with recent progress of 4Kscore test could fuel rapid advancements of diagnostic operation.** The 4Kscore test is a prostate cancer blood test to accurately identify the high risk patients who could develop aggressive disease. The added sales force from BRL could potentially expand 4Kscore sales to specialists and primary care doctors alike. Claros1 point-of-care rapid diagnostic tests are the next-in-line product. BRL's service revenue assuming conservative growth, combined with OPK's sales could place OPK in cash positive position starting in 2016.
- **Seasoned management and strategic investment is a plus.** OPK is not a typical biotech or diagnostic company. It is headed by CEO Dr. Phillip Frost, who has successfully led several pharmaceutical companies, such as IVAX and Teva. Coupled with concentrated insider ownership and strategic investments, we believe these bode well for providing shareholder with substantial upside.
- **Upside remains at the current valuation.** Based on multiple drivers in place, we believe OPK shares remain undervalued at their current level. Our \$22 price target is based on DCF analysis at 12% discount rate and 7% terminal growth rate.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.26A	-0.09A	-0.08	0.03	-0.37	N.A.
FY-14A	-0.11	NA	NA	-0.12	-0.41	N.A.
FY-13A	-0.11	NA	NA	NA	-0.32	N.A.
FY-12A	-0.03	-0.04	-0.03	-0.01	-0.11	N.A.

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker:	OPK
Rating:	Buy
Price Target:	\$ 22.00

Trading Data:

Last Price (08/11/2015)	\$ 13.45
52-Week High (6/3/2015)	\$ 19.20
52-Week Low (10/13/2014)	\$ 8.02
Market Cap. (MM)	\$ 6,236
Shares Out. (MM)	464

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Investment Thesis

Our \$22 price target is supported by DCF analysis.

Our key investment thesis of OPK is that the company is on the verge of starting an era with the potential for multiple products to receive approval and launch within the next 24 months

- **We are initiating coverage of OPKO Health (OPK) with a Buy rating and a 12-month price target of \$22.** OPKO Health is a diversified medical product company that develops and commercializes diagnostics and therapeutics. The company is in a rapid expansion stage with four products already in or likely to reach the market within the next two years. OPK is led by Dr. Phillip Frost, who has successfully founded several pharmaceutical companies, such as IVAX, which was acquired by Teva. He also was the Chairman of the Board of Teva from March 2010 to February 2015 and oversaw its transition from a pure generic player to a provider of broader drug offerings. OPK is not a typical biotech or diagnostic company. With concentrated insider ownership and seeking opportunistic and strategic investment and asset acquisitions continually, we believe it could provide substantial upside to investors.
- **OPK is on the cusp of a major transformation in both the diagnostic and pharmaceutical operations, potentially resulting in the start of rapid revenue growth over the next few years.** Our key investment thesis of OPK is that the company is on the verge of starting an era with the potential for multiple products to receive approval and launch within the next 24 months. Over the last few years, the company has continuously assembled and further developed many assets to build a comprehensive portfolio in diagnostics and pharmaceuticals. OPK developed some assets in house and outlicensed others to maximize shareholder value. As such, we anticipate the company could start generating substantial revenue and become cash positive or even profitable starting in 2016. OPKO Health, in our opinion, is poised to reach a potential inflection point and become a company with both commercialization and R&D activities. On the diagnostic side, the acquisition of Bio-Reference Laboratories (BRL) could facilitate the sales of the company's lead diagnostic product, the 4Kscore prostate cancer test, and the upcoming Claros1 point-of-care diagnostic tests going forward. BRL also brings in substantial and steadily growing revenue that potentially enables OPK to become cash positive near term. On the pharmaceutical side, we believe development is maturing rapidly with three products that could enter the market within the next 24 months and with total peak sales potential exceeding \$2.0+ billion. Two out of the three products are partnered. Earlier stage pipeline products are also very interesting with large market potential.
- **Bio-Reference Laboratories acquisition coupled with recent progress of the 4Kscore prostate cancer test could fuel rapid advancements of diagnostic/clinical service operation.** OPK recently acquired Bio-Reference Laboratories (BRL), which is the third largest full service clinical laboratory in the U.S., for \$1.47 billion and the deal

Bio-Reference Laboratories acquisition coupled with recent progress of the 4Kscore prostate cancer test could fuel rapid advancements of diagnostic/clinical service operations.

Three leading products that could enter the market over the next 24 months are Rayaldee, Rolapitant and hGH-CTP (MOD-4023).

Rayaldee is well differentiated from other vitamin D deficiency treatments on the market and Phase III study results met the primary endpoint. We estimate potential annual peak sales of \$600MM.

We estimate rolapitant potential annual peak sales of ~\$400MM and we assume OPK receives a royalty payment of 14%.

hGH-CTP (MOD-4023) pivotal Phase III study in adult GHD is ongoing with top-line results expected in 2H16 and potential product launch in 2H17. We believe MOD-4023 could potentially be the first long acting growth hormone to market and we estimate the potential peak sales could reach \$1.1+ billion

is expected to close in late August. Bio-Reference not only affords OPK an expanded revenue stream but also provides the vertical integration to enable OPK to expand the sales of its lead diagnostic products, the 4Kscore test and the upcoming Claros1 point-of-care tests. OPK launched the 4Kscore test in 2014, and the test recently has been included in the NCCN guideline for early prostate cancer detection – a very positive development that could accelerate buy-in by physicians and facilitate reimbursements by private and public payers. The company has started billing discussions with Medicare administrative contractors (MACs) for Medicare reimbursement. Given all 4Kscore tests are currently performed at the Nashville, TN facility, potential national coverage could be achieved if the test received coverage by one local MAC, which can reimburse for patients nationwide, without the need to apply for coverage from all other MACs. We estimate the 4Kscore test could receive Medicare coverage in 2016. Going forward, the test will be conducted at the Elm Park, NJ facility. BRL will contribute steadily growing clinical laboratory service revenue to OPK top-line and their genetic and genomic data from the GeneDx operation could be a bright spot for future growth.

- Pharmaceutical operations with three products potentially entering the market over the next two years with deep pipeline behind.** Over the last few years, OPK has assembled a broad spectrum of pharmaceutical assets to build a portfolio with a well-integrated pharmaceutical operations supply chain. Three leading products that could enter the market over the next 24 months are Rayaldee, Rolapitant and hGH-CTP (MOD-4023). Rayaldee is a modified release oral vitamin D prohormone (25-hydroxyvitamin D) that intends to treat secondary hyperparathyroidism (SHPT) in stage 3 or 4 chronic kidney disease (CKD) patients with vitamin D insufficiency. The PDUFA date is scheduled on March 29, 2016, with potential product launch in mid-2016. Rayaldee is well differentiated from other vitamin D deficiency treatments on the market and Phase III study results met the primary endpoint. We estimate potential annual peak sales of \$600MM. Rolapitant is NK-1 receptor antagonist with potential to treat chemotherapy-induced nausea and vomiting (CINV). OPK out licensed rolapitant to Tesaro for further development. Results from three Phase III studies met the primary endpoint and the drug could potentially get approval in 3Q15 (PDUFA date: Sept. 5, 2015) and enter the market in 4Q15. We estimate potential annual peak sales of ~\$400MM and we assume OPK receives a royalty payment of 14%. hGH-CTP (MOD-4023) is a long-acting human growth hormone potentially for growth hormone deficiency treatment and the pivotal Phase III study in adults is ongoing with top-line results expected in 2H16 and potential product launch in 2H17. OPK out licensed MOD-4023 to Pfizer and we believe it will be part of product life cycle management solution for Pfizer's Genotropin. We believe MOD-4023 could potentially be the first long acting growth hormone enters the market and we estimate the potential peak sales could reach \$1.1+ billion. OPK is entitled to a royalty and later switch to profit-sharing from MOD-4023 sales. Further, the addition of smaller assets, such as EirGen Pharma and Prolor Biotech, to OPK's portfolio could further strengthen the infrastructure, such as

R&D and manufacturing value-chain, and for pharmaceutical development.

- **Strategic investment could create upsides in multiple ways.** In addition to developing and commercializing healthcare products, OPK also participates in strategic investments in early stage companies that it perceives to have valuable proprietary technology and significant potential to create value for OPKO shareholders. Given OPK frequently, over time, takes a major position in some of these investments; the company could have the option to acquire these assets for further development in house (such as Prolor Biotech). OPK also has the option to further grow or facilitate partnering out these assets to maximize OPK shareholder value. In addition, we believe OPK's operations outside of the U.S., in both commercialization (such as in emerging markets) and product development could provide shareholders additional upside and risk diversification.
- **Valuation is favorable.** We believe OPK shares are undervalued, based on diversified multiple shots on goal coupled with a great potential for the four assets to enter the market or to expand sales. It is noted that 2016 and beyond are likely to be catalyst-rich for OPK shareholders. We believe OPK shares could materially appreciate should the outcome of some of these events be positive. Accordingly, our \$22 price target is supported by DCF analysis. We are recommending OPK shares to long-term oriented investors with moderate risk tolerance.

Company Description

OPKO Health is a healthcare product company that focuses on both therapeutic and diagnostic products. OPK has four lead advanced stage products in development in-house as well as by partners. The company recently acquired the third largest diagnostic testing laboratory in the U.S., Bio-Reference Laboratories to strategically grow OPK's leading 4Kscore prostate cancer diagnostic test and the upcoming Claros1 point-of-care diagnostic tests. BRL also contributes to the expansion of OPK's revenues substantially and is likely to place OPK in a cash positive, if not profitable, position near term. On the pharmaceutical side, OPK has three products that could reach the market over the next 24 months. Chronologically led by Rolapitant, which is out licensed to Tesaro as a treatment for chemotherapy induced nausea and vomiting (CINV), the drug could get approval in 3Q15 (PDUFA date: Sept. 5, 2015) and enter the market in 4Q15. Rayaldee, a modified released oral vitamin D prohormone (25-hydroxyvitamin D) intended to treat secondary hyperparathyroidism (SHPT) in stage 3 or 4 chronic kidney disease (CKD) patients with vitamin D insufficiency will have the PDUFA date in 1Q16 (March 29, 2016) and potential product launch in mid-'16. MOD-4023 (hGH-CTP) is a long-acting human growth hormone potentially for growth hormone deficiency treatment. The pivotal study is ongoing with top-line results expected in 2H16 and potential product launch in 2H17. Several earlier stage pipeline products (MOD-5014 or factor VIIa-CTP and oxyntomodulin) are also in development. OPK also participates in strategic investment to either in-licensing (acquisition) or maturing the product development to maximize OPK shareholder value. Together, OPK is in a transition from a mainly a pure product developer to commercialization operations on track to profitability, with larger revenue growth anticipated over the next several years.

Anticipated milestones in 2015 and beyond

Product	Indication	Event	Timing	Importance
Rayaldee	SHPT in CKD Stage 3-4 patients	Start to build M&S organization	2H15	***
		PDUFA date	March 29, 2016	****
		Product launch	Mid-2016	***
		Potential include in for formulary of healthcare plans	2017'	****
Rolapitant	Chemotherapy -induced nausea and vomiting (CINV)	PDUFA date	September 5, 2015	****
		Potential product launch	4Q15	***
hGH-CTP (MOD-4023)	hGH deficiency	Report of Phase III study top-line results	2H16	****
		Potential product launch for adult hGH deficiency	2H17	***
		Report of Phase III pediatric study top-line results	2018	****
4Kscore test	Prostate cancer diagnostics	Category 1 CPT code approval decision	4Q15/1Q16	***
		CMS reimbursement decision	2016	****
		Potential private payer reimbursement decision	2016 - 2017	****
Claros 1 testosterone test	POC testosterone test	Potential 510(k) filing	1H16	***
		Potential approval	2017	****
Claros 1 PSA test	POC PSA test	Modular PMA filing	1H16	***
		Potential approval	2017	****
Claros 1 vitamin D test	POC vitamin D test	Potential 510(k) filing	4Q16	****
		Potential approval	2017	****
MOD-5014 (IV)	Hemophilia A/B with inhibitors	Potentially report Phase I/IIa study top-line results	4Q16	***
		Potentially start Phase II/III study	1Q17	***
		Potentially report Phase II/III study results	2Q18	****
MOD-5014 (s.c)		Potentially start Phase I study	1H16	***
		Potentially report Phase I study results	1H16	****
		Potentially start Phase II study	4Q16	***
MOD-6031 (Oxyntomodulin)	obesity	Potentially report Phase II study results	4H17	***
		Potentially start Phase I study	1Q16	***

**** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative

Source: Laidlaw & Company and company presentation.

OPKO Health Pipeline

Product	Indication	Preclinical	I	II	III	Reg	Launch	Comments	
Rayaldee (CTAP101)	SHPT (CKD Stage 3-4 patients)								PDUFA date: March 29, 2016
hGH-CTP	hGH deficiency (adult)								Potential NDA filing in 2H16
	hGH deficiency (pediatric)								
Alpharen	Hyperphosphatemia (ESRD patients)								
Rolapitant	CINV								PDUFA date: September 5, 2015
Factor VIIa-CTP	Hemophilia								Phase IIa trial top-line results in 2H16
Sci-B-Vac	Hepatitis B (CKD Stage 5 patients)								
CTAP201	Mild to moderate SHPT (ESRD patients)								
Oxyntomodulin	Diabetes, obesity								Phase I trial to start in 1Q16
AntagoNAT Platform	Cancer, CV, metabolic and orphan disease								
CYP24 Inhibitors	SHPT, CKD, cancer								Phase I trial to start in 4Q16

Source: Laidlaw & Company and company presentation

OPK Is On the Verge of Revenue Growth from Pharmaceutical and Diagnostic Divisions Near Term

OPK is a medical products company that provides pharmaceutical and diagnostic products

OPKO Health is a unique healthcare product company given: 1) it develops and commercializes both pharmaceutical and diagnostic products with substantial market potential; 2) it engages in strategic investments in an opportunistic- or strategic-driven manner, frequently taking a significant equity position, and potential to acquire or grow these opportunities and create a broad and diversified portfolio; and 3) it is led by Dr. Phillip Frost, who has an established track record of building pharmaceutical companies successfully, and the company has a concentrated insider ownership. Together, we believe these bode well for providing shareholders with well diversified and risk balanced product offerings and business model.

Besides the unique setup of the OPK operation, another investment highlight for OPK is that the company is on the verge of significant revenue growth from both the diagnostic (plus laboratory service) and potential pharmaceutical product launches. The pharmaceutical product pipeline is maturing with three products potentially to be launched over the next 24 months. We are also encouraged by the advancement of their Factor VIIa-CTP (MOD-5014) for treating hemophilia patients developing inhibitors with the Phase I/II trial underway. On the diagnostic side, the acquisition of Bio-Reference Laboratories provides a creditable platform to expand the sales of the 4Kscore test and the upcoming point-of-care Claros1 immunoassay. Bio-Reference also contributes service revenue that could place OPK in cash positive position possibly starting 2016.

On the potential revenue from pharmaceuticals, we anticipate a positive decision by the FDA on the PDUFA date (September 5, 2015) for Rolapitant in chemotherapy-induced nausea and vomiting (CINV), followed by a product launch by Tesaro in 4Q15. We estimate the annual peak sales could potentially reach ~\$400MM, and OPK is entitled to a royalty payment of \$50+MM assuming a rate of 14%. We estimate a high probability of approval for Rayaldee at its PDUFA date (March 29, 2016). If approved, we anticipate OPK will launch the product shortly thereafter and we estimate annual peak sales reach ~\$600MM. For long-acting human growth hormone (MOD-4023 or hGH-CTP), we anticipate the top-line results from the Phase III study could be available in 2H16. If positive as we project, Pfizer is likely to file a BLA in 2H16 with potential approval and product launch in 2H17. We estimate the

annual peak sales of MOD-4023 could reach \$1.1+ billion and provide OPK annual profit-sharing revenue up to \$200MM assuming a 25% share of the profits. The earlier stage pipeline includes Factor VIIa-CTP (MOD-5014) in hemophilia with inhibitors which is under a Phase II study; and long acting oxyntomodulin (MOD-6031) in obesity which will start a Phase I study in 1Q16. The commercial outlook for both programs could be significant.

On the potential revenue from diagnostic and clinical service laboratory, we estimate the peak annual revenue of the 4Kscore test could reach \$300+MM. Further, we project Bio-Reference Laboratories' existing sales to grow annually at a conservative 14% (16% over the last two years) going forward with annual sales reaching \$1.5 billion by 2019. OPK could become cash positive and, depending on non-cash expenses; it even could be profitable in 2016, in our projection – mainly driven by the combined revenue from BRL in laboratory service and OPK in product sales. The margin initially could be low given the majority top-line contribution comes from laboratory service revenue. However we believe it could improve substantially as the product mix changes with significant cash flow derived from royalty payments and pharmaceutical and more profitable diagnostic sales.

Together, we believe potential near-term revenue expansion, coupled with rather unique strategic investment practices that could afford upside opportunity and a unique investment opportunity with a favorable risk / benefit profile.

After Bio-Reference Acquisition, OPK is Becoming a Material Player in Diagnostic and Test Provider with 4Kscore Sales Leading the Way

The two major diagnostic products are the 4Kscore test and the Claros1 immunoassay instrument system. The former is a prostate cancer reflex test, while the latter is a novel microfluidics-based system that could provide multiple point-of-care diagnostic products

By providing much accurate risk assessment (vs. PSA test and other similar tests, for example), the value proposition of the 4Kscore test is for patients who are considered high risk based on the 4K score test result, to benefit from a decision to undergo a biopsy procedure for confirming their disease status.

For the dominant majority of patients who have already undergone a PSA test but judged to be low-risk based on 4Kscore results; they could avoid taking the unnecessary biopsy procedure, and avoid potential procedure-associated risks, such as infection and hospitalization.

Diagnostics is one of the two major product offerings beside pharmaceuticals as key value driver for OPK shareholders. The two major diagnostic products are the 4Kscore test and the Claros1 immunoassay instrument system. The former is a prostate cancer reflex test, while the latter is a novel microfluidics-based system that could provide multiple point-of-care diagnostic products. Reflex test refers to laboratory test performed subsequent to an initially prescribed test for the purpose of providing more conclusive results to facilitate decision-making. Specifically, a reflex test is needed for making a more educated and actionable decision when, despite the result from the initial test meeting pre-determined criteria, it remained inconclusive. OPK recently acquired Bio-Reference Laboratories, which is the third largest full service clinical laboratory in the U.S. Supported by this vertical integration, we anticipate OPK could significantly enlarge its diagnostic operation from the substantial sales organization and external accounts expansion to increase the sales of OPK's own diagnostic test products. OPK's total revenue also is boosted significantly after adding BRI's current clinical laboratory services sales.

Expanded diagnostic operation could facilitate the growth of 4Kscore prostate test

What is the 4Kscore test? The 4Kscore test is a prostate cancer blood test that allows accurate identification of patients who have a high risk developing aggressive prostate cancer. By providing much more accurate risk assessment (vs. PSA test and other similar tests, for example), the value proposition of 4Kscore test is for patients who are considered high risk based on the 4K score test result, to benefit from a decision to undergo a biopsy procedure for confirming their disease status. For the dominant majority of patients who have already undergone a PSA test but judged to be low-risk based on 4Kscore results; they could avoid taking the unnecessary biopsy procedure, and avoid potential procedure-associated risks, such as infection and hospitalization. Together, 4Kscore test results could better facilitate the patient and physician experience, making a more logical and potentially cost-saving decision for their next cause of action.

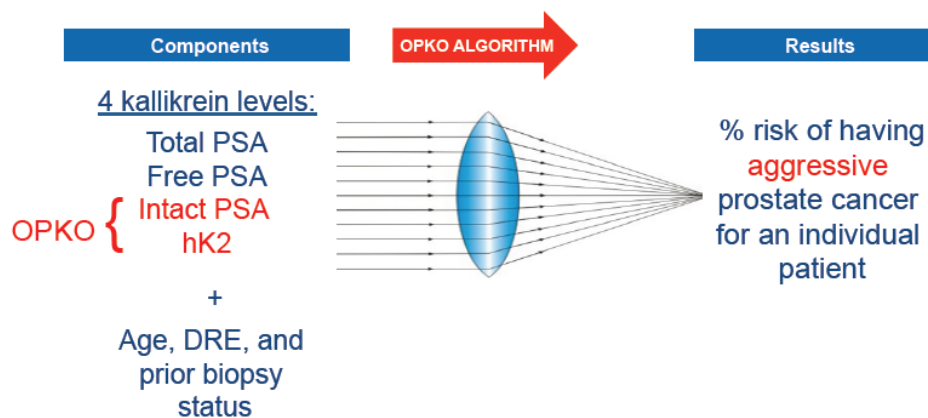
Launched in March 2014, the 4Kscore test is a four kallikrein biomarkers panel blood test coupled with clinical information [patient's age, digital rectal examination (DRE) status, and history of prior biopsy status] and uses a

The 4Kscore test is a four kallikrein biomarkers panel blood test coupled with clinical information and uses a proprietary algorithm to calculate the patient's individual risk for aggressive prostate cancer (Gleason score >7).

The 4Kscore test does not provide a diagnosis of prostate cancer, it affords the assessment of probability of developing cancer in the future

proprietary algorithm to calculate the patient's individual risk for aggressive prostate cancer (Gleason score ≥ 7). It also provides a high negative predictive value to exclude those patients who do not have aggressive prostate cancer. The four kallikrein biomarkers are total PSA, free PSA, intact PSA and human kallikrein 2 (hK2) (Figure 1). The 4Kscore test does not provide a diagnosis of prostate cancer; it affords the assessment of probability of developing cancer in the future.

Figure 1: 4Kscore test is a multiplex diagnostic

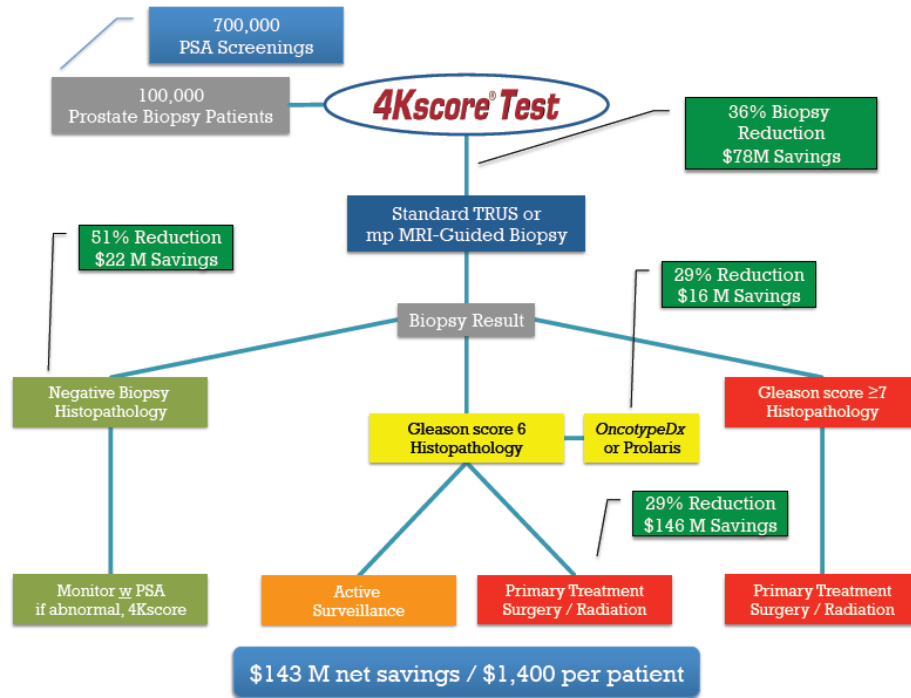


Source: Company presentation

Although the PSA test is the first-line screening for men suspected to have prostate cancer; and this test has had substantial success in identifying earlier stage cancer; the predictive value of the test alone remains controversial due to its low sensitivity (high false positive rate) and the consequent decision of over-treatment of indolent disease. In the U.S., it is estimated that near 30 million PSA tests are conducted each year and approximately 20% might have higher readings. Among those higher readings, it results in ~1 million biopsies take place in the U.S. annually for further confirming their disease status. However, it is estimated only 200,000 cases of high grade aggressive tumors (Gleason scores ≥ 7) were identified that require subsequent treatment. As such, a substantial portion (~ 80%) of biopsies might not be necessary and a better reflex test with a more accurate predicative value is needed.

In addition to the potential benefit of performing prostate biopsy prudently at the patient level, eliminating potential unnecessary biopsy procedures in patients who have very low probability developing aggressive prostate cancer should also benefit insurance payers. OPK presented a scenario analysis of a healthcare plan that includes 700,000 PSA screenings, leading to an estimated 100,000 biopsy procedures annually. Should the 4Kscore test be used, it potentially could reduce unnecessary biopsies, and realize a potential \$143MM in net savings (\$1,400 per patient, Figure 2).

Figure 2: A scenario analysis for a healthcare plan on saving from employing 4Kscore test

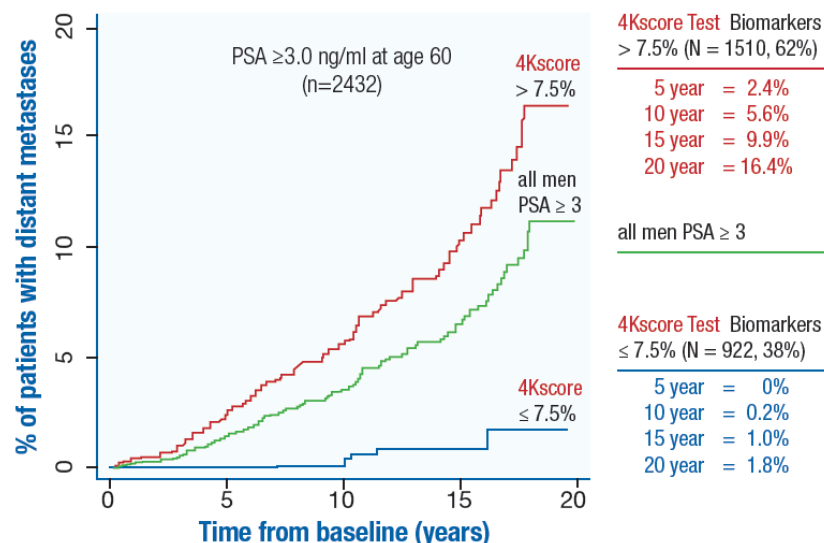


Source: Company presentation

Clinical study results afford strong predictive value. The clinical effectiveness of the 4Kscore test is validated via 10 years of clinical research conducted by Memorial Sloan Kettering Cancer Center and leading international cancer centers, supported by 11 peer-review publications. The test predicts a high probability (16.4%) of developing distant metastases within 20 years if the 4Kscore >7.5%; while the probability in 20 years is rather low (1.8%) if 4Kscore ≤7.5% (Figure 3)

The 4Kscore test predicts a high probability (16.4%) of developing distant metastases within 20 years if the 4Kscore >7.5%; while the probability in 20 years is rather low (1.8%) if 4Kscore <7.5%

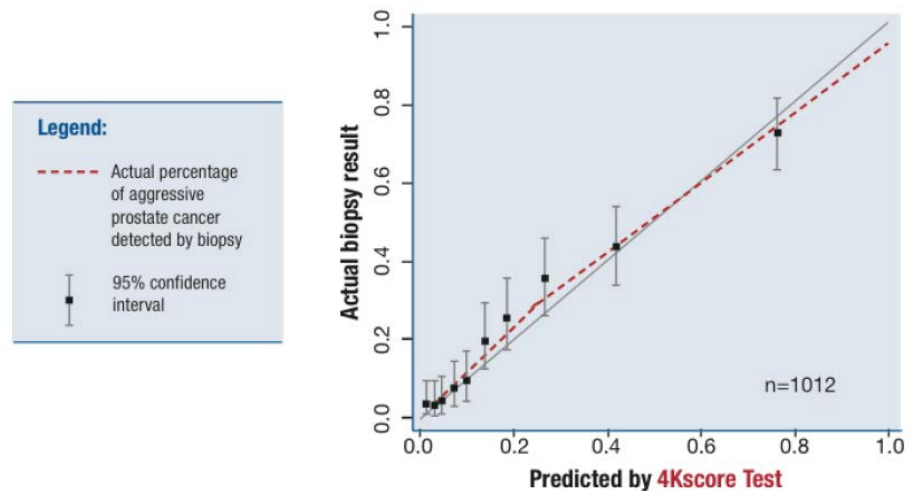
Figure 3: 4Kscore test provide metastases prediction within 20 years



Source: Company presentation

Further, the risk of aggressive prostate cancer predicted by the 4Kscore test is confirmed by prostate biopsy as both curves are essentially overlapped (Figure 4).

Figure 4: 4Kscore test predicted risk is confirmed by biopsy



The risk of aggressive prostate cancer predicted by the 4Kscore test is confirmed by prostate biopsy as both curves are essentially overlapped

The area under the curve (AUC) of the 4Kscore was 0.82. As a reference, the AUC for the PSA test is 0.69. At the 4Kscore test cutoff of 7.5%, the sensitivity and specificity is 93% and 45%, respectively.

Source: Company presentation

The clinical utility of the 4Kscore test was further validated in the U.S. by a prospective blinded multi-center study with data reported at the 2014 American Urological Association (AUA) annual meeting. The study included 1,012 patients and the results demonstrated the area under the curve (AUC) of the 4Kscore was 0.82. A larger AUC suggests better accuracy for predicting aggressive prostate cancer. As a reference, the AUC for the PSA test is 0.69. At the 4Kscore test cutoff of 7.5%, the sensitivity and specificity is 93% and 45%, respectively.

We believe 4Kscore is a best-in-class reflex test for potential pre-biopsy prostate cancer patients given the robustness of its clinical results. The other marketed test is the blood-based Prostate Health Index (PHI) developed by Beckman Coulter and distributed by Innovative Diagnostics. The sensitivity and specificity of the PHI test is 71% and 26%, respectively; while AUC is equal to 0.72. A urine-based Prostarix test developed and marketed by Metabolon is no longer available in the market based on our due diligence.

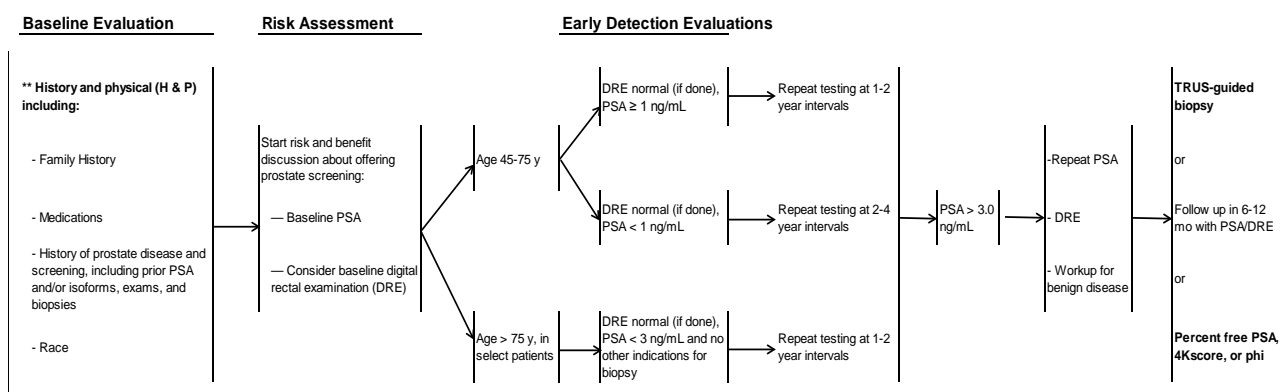
NCCN in June 2015 reported to include 4Kscore as a recommended test in the 2015 NCCN Guidelines for Prostate Cancer Early Detection. We view the recommendation as an important endorsement as this could expand the buy-in not only by urologists but other medical practitioners, such as oncologists and general practitioners.

National Comprehensive Cancer Network (NCCN) in June 2015 reported to include 4Kscore as a recommended test in the 2015 NCCN Guidelines for Prostate Cancer Early Detection (Figure 5). We view the recommendation by NCCN as an important endorsement as this could expand the buy-in not only by urologists but other medical practitioners, such as oncologists and general practitioners. It also enhances the buy-in from Centers for Medicare & Medicaid Services (CMS) and private payers for future reimbursement discussions.

The 4Kscore test currently has received an administrative procedural terminology (CPT) code. OPKO is applying for a category one CPT code and the

review by CMS is expected in October 2015 with a potential decision in late 2015 or early 2016. If granted, which we believe has a high probability especially after being included in the NCCN guideline, the 4Kscore test would be reimbursed automatically by CMS for Medicare. The potential activation of the category one CPT would be in early 2017. The company is in the process of discussions with Medicare administrative contractors (MACs) for Medicare reimbursement. Given all 4Kscore tests are currently performed at the Nashville, TN facility, a potential national coverage could be achieved if the test received coverage by the local MAC and without the need to apply for coverage from all other MACs. We estimate the 4Kscore test could receive Medicare coverage in 2016. Going forward after completed BRL acquisition, we believe future 4Kscore test analysis would be done at the Elmwood Park, NJ facility given its substantially larger capacity.

Figure 5: NCCN 2015 guidelines for prostate cancer early detection



Source: NCCN and Laidlaw & Company equity research

We anticipate the two different arms of BRL of the sales group would contribute differently for 4Kscore test market penetration. For the one that targets various specialists nation-wide for esoteric testing, they could help to expand the sales to various oncologist and other relevant specialist groups

For the group that targets primary care physician mainly for routine tests, they could start to promote 4Kscore test to their accounts, given the majority of the PSA tests prescribed in the U.S. are from non-specialist but general practitioners.

We believe market penetration of the 4Kscore test in the future could benefit significantly from the marketing and sales operation acquired from BRL. This is especially for medical practitioners outside of urologists, given they are the only specialists approached by the current OPK sales team and the acceptance from urologists is very encouraging.

Specifically, we anticipate the two different arms of BRL of the sales group would contribute differently for 4Kscore test market penetration. For the one that targets various specialists nation-wide for esoteric testing, they could help to expand the sales to various oncologist and other relevant specialist groups given their size (~100) is much larger than that of the current OPK team. For the second group that targets primary care physician mainly for routine tests, they could start to promote 4Kscore test to their accounts, given the majority of the PSA tests prescribed in the U.S. are from non-specialist such as general practitioners. Should this endeavor be successful, the sales growth of 4Kscore tests could be very significant. BRL's sales force for primary care is more focused on the Northeast of the U.S., especially New York, New Jersey and part of Pennsylvania. In addition, BRL has over 600 blood drawing sites located in different doctors' offices in the company's focus territories and they provide

significant value due to the ease of access by patients and potential prescribing physicians.

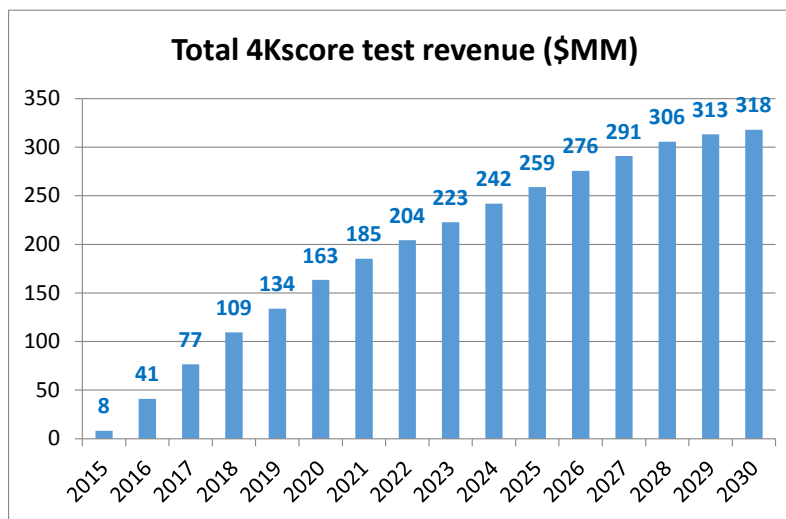
4Kscore market model assumptions: It is estimated that in the U.S., approximately one million prostate biopsies have been carried out each year. We assume these patients could be the basis of our model as they could benefit from the 4Kscore test to make a more educated decision for the next course to take. An even larger potential market might exist for some patients with higher PSA scores along with other unfavorable conditions, who could also benefit from a 4Kscore test even though they have not yet been sent for a prostate biopsy. Given the self-paid and the list price is \$395 and \$1,185, respectively, and Medicare billing payment could be in the range between 50% and 125%, we assume \$950 as the 4Kscore test price.

Figure 6a: 4Kscore prostate diagnostic test revenue model

4Kscore as prostate diagnostic revenue model																
	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Prostate biopsy cases	846,600	863,532	880,803	898,419	916,387	934,715	953,409	972,477	991,927	1,011,765	1,032,001	1,052,641	1,073,694	1,095,167	1,117,071	1,139,412
% used 4Kscore test	2%	5%	9%	12%	15%	17%	19%	20%	21%	22%	23%	23%	24%	24%	24%	23%
Prostate pt with 4Kscore	14,391	43,177	79,272	111,404	133,793	160,771	179,241	194,495	208,305	222,588	234,264	245,265	254,465	262,840	264,746	264,344
Costs (\$)	523	950	966	983	999	1,016	1,034	1,051	1,069	1,087	1,106	1,124	1,144	1,163	1,183	1,203
Total 4Kscore test revenue (\$MM)	8	41	77	109	134	163	185	204	223	242	259	276	291	306	313	318

Source: Laidlaw & Company estimates

Figure 6b: 4Kscore prostate diagnostic test revenue model



Source: Laidlaw & Company estimates

Claros 1 rapid testing platform is used as a point-of-care diagnostic in physicians' offices

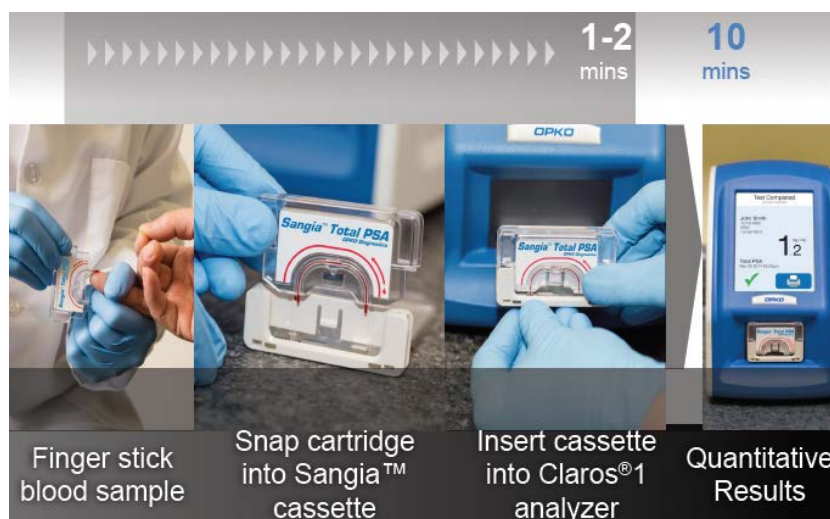
OPK is also developing the Claros1 immunoassay instrument system as point-of-care rapid diagnostic tests to offer high performance and complex blood tests suitable for physicians' offices. Claros1 is a novel microfluidics-based system

consisting of a credit card-sized disposable test cassette that works with a small desktop analyzer (Figure 7). Given Claros1 immunoassay instrument system could potentially provide high performance (similar to central laboratory-grade) blood-based test results rapidly and transmit the outcome to physician’s offices or hospital nurses’ stations, it could circumvent the need for and save the time of sending out samples for some routine tests to an off-site centralized laboratory for analysis.

OPK is scheduled to develop a number of Claros1 tests going forward. They include a testosterone test with 510(k) filing expected in 1H16. A PSA test for the purpose of detection claim is scheduled for a modular PMA filing in 2H16. Both tests could potentially receive approval in 2017 as it might take longer for the agency to review them.

OPK is scheduled to develop a number of Claros1 tests going forward. They include a testosterone test with a 510(k) filing expected in 1H16. A PSA test for the purpose of detection claim is scheduled for a modular PMA filing in 2H16. Both tests are relatively straightforward and the company plans to use them as initial examples to allow the FDA become more familiar with the Claros1 platform. Both tests could potentially receive approval in 2017 as it might take longer for the agency to review them. There are 15 million testosterone tests and 30 million PSA tests conducted annually in the U.S. Other Claros1 tests in the pipeline under development include renal panel tests: vitamin D (70 million tests in the U.S.), iPTH and cystatin C. Further, a Lyme disease test is also under consideration. OPK could file a 510K for vitamin D test in late 2016 with possible approval in 2017 when Royaldeed inclusion in formulary could potentially already in place.

Figure 7: Claros 1 rapid testing platform



Source: Company presentation

Bio-Reference acquisition could place OPK as an important diagnostic player

In 2Q15, OPK announced the acquisition of Bio-Reference Laboratories (BRL) for a total value of \$1.47 billion.

In 2Q15, OPK announced the acquisition of Bio-Reference Laboratories (BRL) for a total value of \$1.47 billion. The transaction is expected to close by the end of August 2015, according OPK’s 2Q15 conference call. After the acquisition,

OPK's diagnostic services will be merged with BRLI's operation throughout the U.S.

Bio-Reference's revenues are divided between two types of services: routine and esoteric testing. Routine tests measure various health parameters, such as the functions of the heart, kidney, liver, thyroid and other organs; and these tests are generally with lower margin but of large quantities. Esoteric testing refers to tests that require sophisticated equipment and materials, highly skilled personnel and professional attention. Esoteric testing is ordered less frequently and priced higher than routine tests. Bio-Reference total revenue between 2014 and 2012 were \$832MM, 715MM and 614MM, respectively. Esoteric testing portion of the revenue over the same period accounted for 68% (or 566MM in 2014), 60% (or \$429MM in 2013) and 60% (or \$368MM in 2012), respectively. With the combined Bio-Reference's service revenue under an organic growth assumption, and OPK's product sales, it is likely to accelerate the pace for OPK to become cash positive or even profitable (determined by the level of non-cash expenses OPK might incur), possibly in 2016, based on our estimate.

Bio-Reference primarily focuses on services provided in esoteric testing, molecular diagnostics, anatomical pathology, genetics, women's health and correctional health care. The company has ~420 sales and marketing personnel. In 2014, Bio-Reference processed ~9.6 million laboratory tests from ~175 patient service centers located in the Northeast (primarily in the New York metropolitan super-regional area) for collection of patient specimens.

In addition to adding revenue to OPK's top line, one of the major strategic objectives of the acquisition is to leverage Bio-Reference's national marketing, sales, and distribution resources to expand sales of OPK's 4Kscore test, and the upcoming Claros1 immunoassay instrument system diagnostic products.

On the oncology side, Bio-Reference operates a national oncology laboratory through its GenPath business unit. It provides services in cancer pathology and diagnostics and molecular diagnostics. We believe operation from this unit and from sales reps for primary care together could facilitate the growth of the 4Kscore test into multiple institutions as described in the prior section.

We also project that the routine testing operation focusing on primary care could potentially facilitate the sales of Claros1 immunoassay instrument system products once they are approved. The physician offices frequently visited by sales reps for routine testing are the key potential users for the Claros1 products. We anticipate OPK to develop creative approaches to sell Claros1 products and minimize any possible cannibalization of similar routine services they currently provided to their accounts.

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We also project that the routine testing operation focusing on primary care could potentially facilitate the sales of Claros1 immunoassay instrument system products once they are approved

Multiple Pharmaceutical Products Could Reach Market Over the Next Two Years Followed by a Robust Pipeline

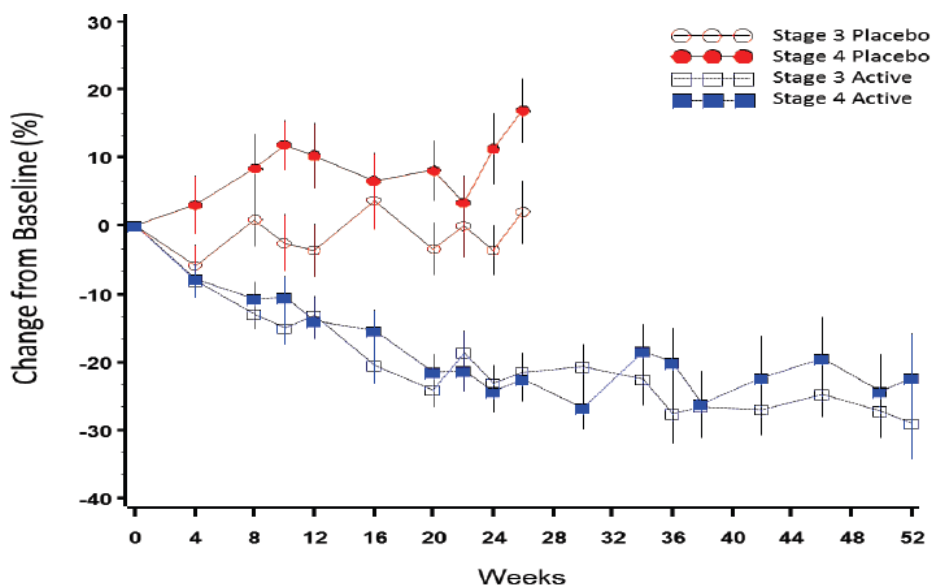
Royaldee leads the renal drug development supported by robust Phase III data

Clinically, Royaldee is OPK's most advanced fully-owned product and the estimated PDUFA date is March 29, 2016. Royaldee (CTAP101) is a first-in-class modified released oral vitamin D prohormone (25-hydroxyvitamin D) therapy intended to treat secondary hyperparathyroidism (SHPT) in stage 3 or 4 chronic kidney disease (CKD) patients with vitamin D insufficiency. In 1Q13, OPK acquired Cytochroma and along with its two Phase III lead products: Royaldee and Alpharen (Fermagate tablets), a non-absorbed phosphate binder to treat hyperphosphatemia in dialysis patients.

Robust Phase III results bode well for potential approval. The company reported robust top-line results in 3Q14 of the two identical Phase III pivotal trials that evaluated Royaldee in stage 3 or 4 CKD patient suffering from secondary hyperparathyroidism (SHPT) with vitamin D insufficiency (VDI). The study met the primary endpoint of changes of at least 30% in plasma iPTH from pretreatment baseline vs. placebo at 6 months (Figure 8).

The Phase III pivotal trials that evaluated Royaldee met the primary endpoint of changes of at least 30% in plasma iPTH from pretreatment baseline vs. placebo at 6 months

Figure 8: Phase III study demonstrated reduction of plasma iPTH

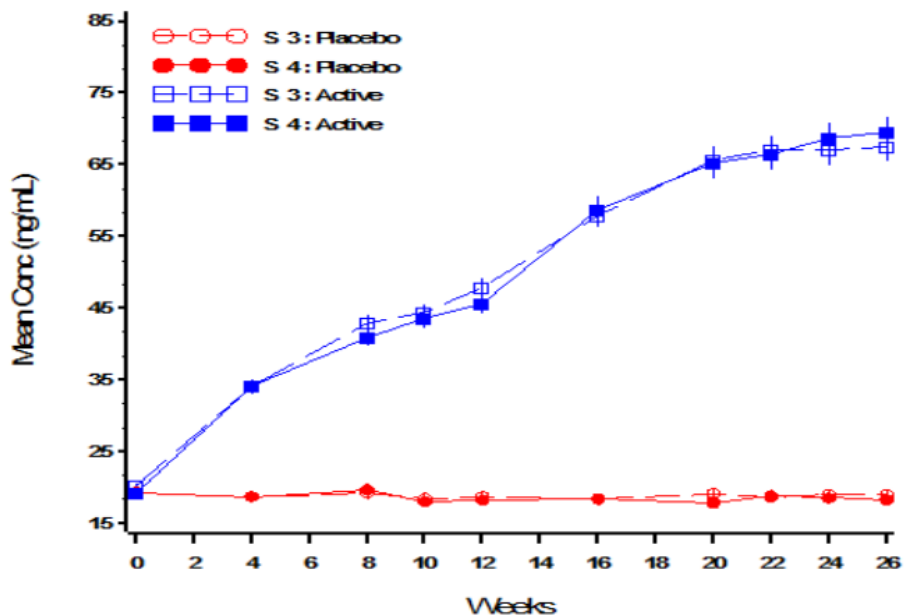


Source: Company presentation

In addition, the study also exhibited changes in serum total 25D to ≥ 30 ng/ml for both stage 3 and stage 4 CDK patients – one of the secondary endpoints (Figure 9).

Figure 9: Phase III study demonstrated increase of plasma 25 hydroxyvitamin D

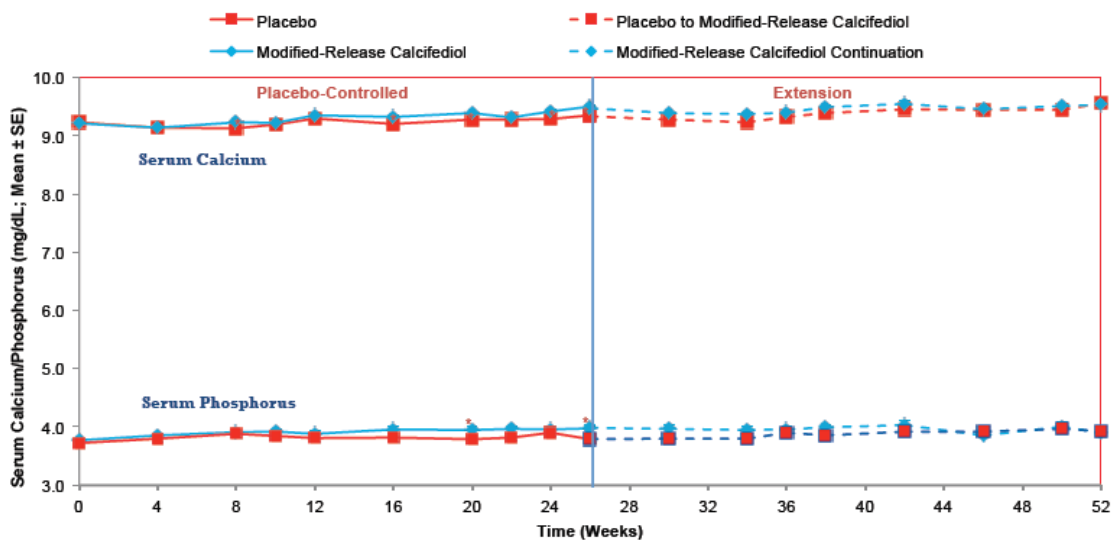
The study also exhibited changes in serum total 25D to ≥ 30 ng/ml for both stage 3 and stage 4 CDK patients – one of the secondary endpoints



Source: Company presentation

Further, the study also illustrated that serum calcium and serum phosphorus levels remain similar between the treated and placebo groups (Figure 10).

Figure 10: Phase III study demonstrated plasma calcium and phosphorus unchanged

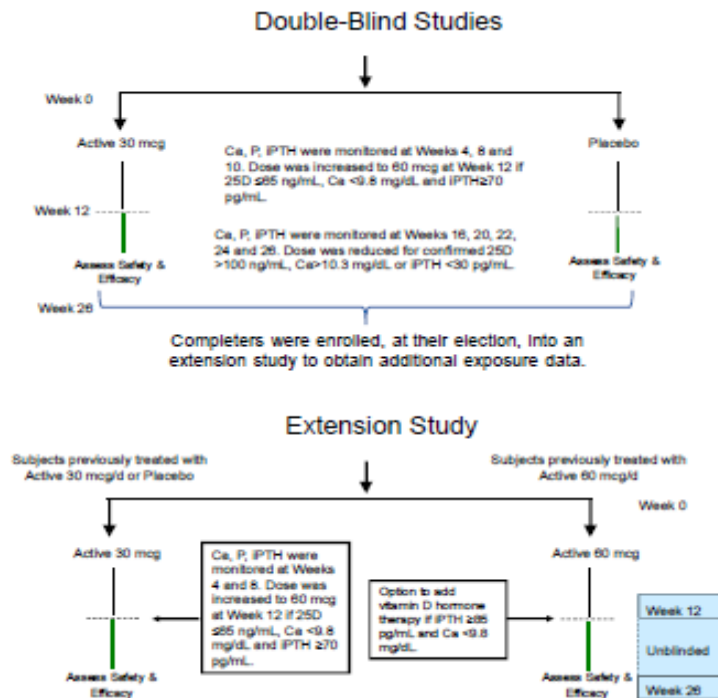


Source: Company presentation

Rayaldee in stage 3/4 CKD patient suffering from SHPT with VDI Phase III study design. It was a randomized, placebo-controlled and 429-patient study. Patients were randomized 2:1 to receive daily bedtime doses of either

Royaldee (either 30 or 60 µg) or a placebo. After the completion of the trial, patients have the option to participate a 6-month extension study with additional Royaldee therapy (Figure 11).

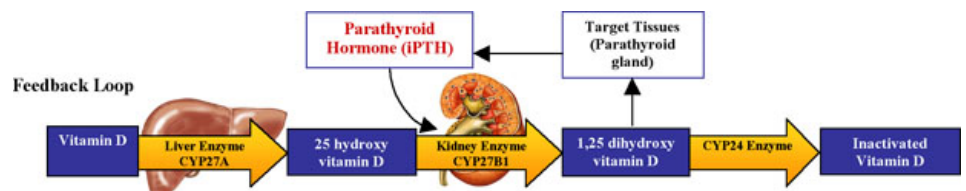
Figure 11: Royaldee in SHPT with VDI of stage 3/4 CKD patient Phase III study design



Source: Company presentation

Basics of vitamin D metabolism. Figure 12 illustrates the metabolism of vitamin D. After vitamin D is converted from 7-dehydrocholesterol (7-DHC) via the UV wave from sunlight or ingested via diet, it is further activated through two sequential hydroxylations: first at carbon 25 by CYP2R1 or CYP27A1 (in the liver) to form 25-hydroxyvitamin D (25(OH)D), and then at carbon 1 by CYP27B1 (in the kidney) to form 1,25-dihydroxyvitamin D (1,25(OH)₂D). 1,25(OH)₂D acts as a potent hormone and binds to the vitamin D receptor (VDR) to regulate a wide variety of genes (Figure 12). An enzyme called CYP24A1 is involved in the catabolism (destruction) of both 25(OH)D and 1,25(OH)₂D.

Figure 12: Vitamin D metabolism



Source: Company presentation

Vitamin D insufficiency (VDI) is associated with chronic kidney disease (CKD) and gives rise to secondary hyperparathyroidism (SHPT) which can lead to loss

Vitamin D insufficiency (VDI) is associated with chronic kidney disease (CKD) and gives rise to secondary hyperparathyroidism (SHPT) which can lead to loss of bone density and elevated rates of fracture in renal patients.

Two general approaches currently used to ameliorate the problem are: 1) vitamin D supplementation to correct vitamin D insufficiency in CKD; and 2) vitamin D hormones to control SHPT.

Cardiovascular complications are the leading cause of death in CKD patients and vascular calcification is a major predictor of subsequent vascular mortality.

Given the propensity of developing vascular calcification, vitamin D hormone therapy in the real world is frequently under-dosed and potentially sub-optimal in efficacy to avoid safety concerns.

of bone density and elevated rates of fracture in renal patients. Potential causes leading to VDI include nutritional inadequacy, proteinuric loss and decreased hepatic synthesis of 25-hydroxyvitamin D and increased expression of vitamin D and its metabolites catabolizing enzyme, CYP24. Two general approaches currently used to ameliorate the problem are: 1) vitamin D supplementation (such ergocalciferol or vitamin D₂ and cholecalciferol or vitamin D₃) to correct vitamin D insufficiency in CKD; and 2) vitamin D hormones (such as calcitriol) to control SHPT. Vitamin D supplementation is generally considered as ineffective since 1) varying initial absorption and subsequent conversion into active vitamin D; and 2) increased vitamin D catabolism due to negative feedback mechanism if the patient received prior high doses of a vitamin D supplement.

The mechanism of action of vitamin D hormone is to activate the vitamin D receptor, resulting in increased intestinal calcium uptake and suppression of iPTH production – the cause of SHPT. The production of regular vitamin D hormone is subject to the body's feedback regulation to avoid the overexposure of vitamin D hormone. Vitamin D hormone therapy (sometime called vitamin D receptor activators or VDRA's), however, could circumvent the feedback regulation and can readily cause over-suppression of iPTH, hypercalcemia and hyperphosphatemia, leading to adynamic bone disease and vascular calcification. Further, vitamin D hormone therapy could also induce CYP24A1 (and FGF23) production and accelerate vitamin D catabolism (based on the evidenced of elevated 24,25-dihydroxyvitamin D), leading to exacerbated vitamin D insufficiency.

Prolonged elevation of iPTH or SHPT could cause 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.

Cardiovascular complications are the leading cause of death in CKD patients and vascular calcification is a major predictor of subsequent vascular mortality. Given the propensity of developing vascular calcification, vitamin D hormone therapy in the real world is frequently under-dosed and potentially sub-optimal in efficacy to avoid safety concerns. Our discussion with management suggested frequent dose of Zemplar is 1 mg/day while product label suggests >2 mg/day. For Hectorol and Rocaltrol, the common prescription is 0.5 mg/day and 0.25 mg/day, respectively, while label suggests 1.5 mg/day and 0.5 mg/day, respectively.

Royaldee, a modified-released (MR) calcifediol (an analog of 25-hydroxyvitamin D) has the benefits of 1) more readily absorbed than vitamin D; and 2) could raise serum 25-hydroxyvitamin D in a gradual manner to physiological levels (≥ 30 to ≤ 100 ng/ml) and avoid excessive induction of CYP24. Figure 13 illustrates the differences between Royaldee and other marketed vitamin B supplement and vitamin D receptor activators.

Figure 13: Rayaldee vs. other vitamin D supplementation and vitamin D hormones

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

Source: Company presentation

Our take on the Rayaldee outlook. We are bullish on the potential success of Rayaldee in treating SHPT in CKD patients with VDI based on: 1) robust clinical data reported bode well for potential approval; 2) well differentiated and logical mechanism of action could position Rayaldee as a better drug that overcomes some of the shortcomings of currently marketed drugs; and 3) by leveraging management’s prior experience in developing and marketing vitamin D therapy in CKD market (for example, CEO of the OPKO Renal Division, Dr. Charles Bishop was CEO of Bone Care International), we believe it could further de-risk the execution risks for the likely Rayaldee launch next year.

Vitamin D deficiency is a major problem for CKD patients, especially in the more severely affected population (Figure 14). The overall market potential for vitamin D therapy is substantial since greater than 80% of stage 4 CKD patients suffer from both VDI and SHPT.

Figure 14: Vitamin D market potential for treating SHPT and VDI is substantial

Stage	Kidney Function	CKD Prevalence	% of CKD Patients with		
			Vitamin D Insufficiency (↓25D)	SHPT (↑ PTH)	Hyperphosphatemia (↑ Phosphorus)
3	Moderate impairment	18.7 Million*	71%	40%	37%
4	Severe impairment	1.4 Million*	83%	82%	50%
5	Failure	0.5 Million*	97%	95%	70%

Source: Company presentation

Management has provided an overview of their Rayaldee commercialization plan. Should the drug receive approval at the PDUFA date; OPK is scheduled to launch the drug in 2Q16. The company plans to hire its marketing & sales

management team in 2H15. OPK plans to build a team with 80 sales representatives. It plans to hire 30-40 sales reps in 1H16 plus 10-15 clinical support specialists (CSSs) in 2Q16; and additional sales reps and CSSs in 2H16 post-launch. The marketing strategy is mainly to target nephrologists (n~5,000) and endocrinologists (n~1,500).

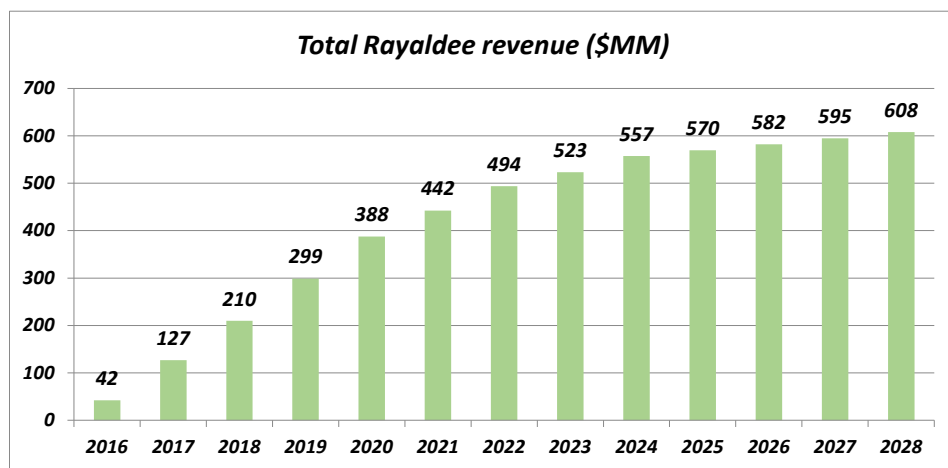
Royaldee market model assumptions: Given the greater propensity of incurring SHPT and VDI in stage 4 and a smaller portion in stage 3 CKD patients, we assume greater penetration for Royaldee in this patient population. We believe our peak sales over \$600MM is reachable since prior Zemplar (paricalcitol) sales have reached ~\$600MM and Royaldee potentially could be a better product.

Figure 15a: Royaldee as Vitamin D therapy in stage 3 and 4 CKD revenue model

Royaldee Revenue Model													
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Stage 3 CKD patients	7,676,000	7,752,760	7,830,288	7,908,590	7,987,676	8,067,553	8,148,229	8,229,711	8,312,008	8,395,128	8,479,079	8,563,870	8,649,509
Stage 3 CKD patients could benefit from Vit D therapy	4,605,600	4,651,656	4,698,173	4,745,154	4,792,606	4,840,532	4,888,937	4,937,827	4,987,205	5,037,077	5,087,448	5,138,322	5,189,705
Stage 4 CKD patients	404,000	408,040	412,120	416,242	420,404	424,608	428,854	433,143	437,474	441,849	446,267	450,730	455,237
% of Stage 3 pt. take Royaldee	0.0%	0.1%	0.2%	0.3%	0.4%	0.4%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%
% of Stage 4 pt. take Royaldee	1.9%	5.0%	8.0%	11.0%	13.6%	15.1%	16.3%	16.5%	17.0%	17.0%	17.0%	17.0%	17.0%
Stage 3 pt. take Royaldee	783	4,652	7,987	11,863	16,774	19,362	22,000	24,689	26,931	27,200	27,472	27,747	28,024
Stage 4 pt. take Royaldee	7,676	20,402	32,970	45,787	57,175	63,946	69,903	71,555	74,371	75,114	75,865	76,624	77,390
Total Royaldee patients	8,459	25,054	40,957	57,649	73,949	83,308	91,903	96,244	101,302	102,315	103,338	104,371	105,415
Price of Royaldee (monthly) (\$)	500	506	512	518	524	531	537	544	550	557	563	570	577
Annual price of Royaldee (\$)	5,000	5,060	5,121	5,182	5,244	5,307	5,371	5,435	5,501	5,567	5,633	5,701	5,769
Total Royaldee revenue (\$MM)	42	127	210	299	388	442	494	523	557	570	582	595	608

Source: Laidlaw & Company estimates

Figure 15b: Royaldee as Vitamin D therapy in stage 3 and 4 CKD revenue model



Source: Laidlaw & Company estimates

A future line extension for Royaldee is to conduct additional Phase III clinical trials in stage 5 CKD (ESRD) patients. In addition, Royaldee is undergoing a Phase I dose escalation study (started in 4Q14) in breast and prostate cancer patients with bone metastases who are receiving anti-resorptive therapy as an adjunctive therapy for the prevention of skeletal-related events.

Additional products in renal product developments. In addition to Rayaldee, another major renal product in development is Alpharen.

Alpharen (Fermagate) is currently completed an earlier Phase III study as a potential treatment of hyperphosphatemia in CKD stage 5 (ESRD) patients. Alpharen is a new and potent non-absorbed phosphate binder; and has been shown to be safe and effective in treating hyperphosphatemia in Phase II and III trials in CKD patients undergoing chronic hemodialysis. Hyperphosphatemia affects ~90% of dialysis patients, and they require ongoing phosphate binder treatment to maintain normal serum phosphorus levels. The company plans to start a Phase III study evaluating Alpharen in hyperphosphatemia in 2016.

CTAP201 is a natural vitamin D hormone and is currently undergoing Phase II study as a potential treatment of mild to moderate SHPT in CKD stage 5 patients (or ESRD).

Rolapitant in chemotherapy-induced nausea and vomiting (CINV) could be the drug most likely to be approved near term if the PDUFA date outcome is positive

Among all products in late development stage, rolapitant would be the one potentially reach the market first, since the PDUFA date is scheduled on September 5, 2015; and all Phase III studies have met the primary endpoint. OPK could receive up to an additional \$110MM milestone and double digit royalty payments should rolapitant receive approval and be commercialized.

Rolapitant, a NK-1 receptor antagonist, is a potential treatment of chemotherapy-induced nausea and vomiting (CINV). OPK initially licensed rolapitant from Schering-Plough in 2009 after the latter merged with Merck as part of the Federal Trade Commission's (FTC) requirement to divest certain assets. OPK out-licensed rolapitant to Tesaro in December 2010 for further development. The company is developing single dose oral and IV formulations of rolapitant; and reported positive Phase III trials of the oral formulation, Tesaro has completed three Phase III rolapitant in CINV studies, reported robust results and filed an NDA in 3Q14.

Three robust Phase III study results bode well for potential approval.

Tesaro conducted three Phase III studies (two in highly emetogenic chemotherapy or HEC and one in moderately emetogenic chemotherapy or MEC, and all met the primary endpoint of complete response (CR) in the delayed phase (the >24-120 hour period following the initiation of chemotherapy). The MEC study results reported in 3Q14 demonstrated rolapitant exhibited a greater CR vs. control (71.3% vs. 61.6%, $p < 0.001$). The CR of overall phase (over the entire 120 hour period) also exhibited statistically significant improvements (68.6% vs. 57.8%, $p < 0.001$); while The CR of acute phase (0-12 hours) exhibited positive improvements but not statistically significant (83.5% vs. 80.3%, $p = 0.143$) (Figure 16). CR of total phase and acute

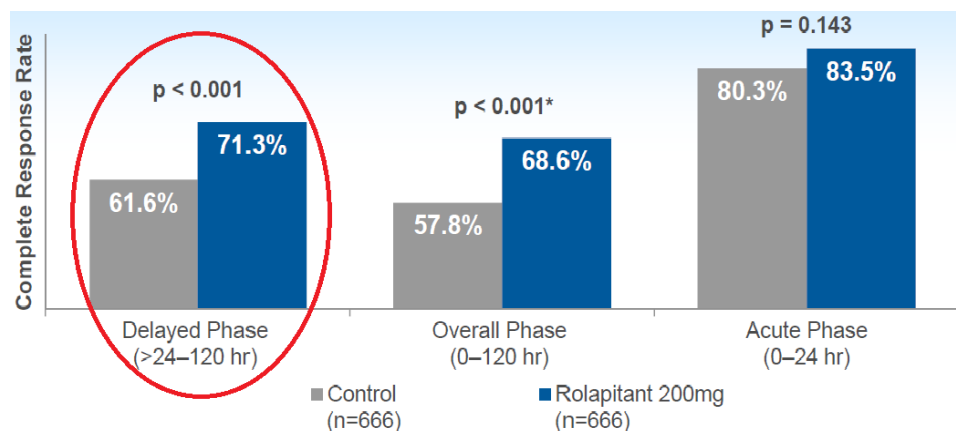
Rolapitant would be the one potentially reach the market first, since the PDUFA date is scheduled on September 5, 2015; and all Phase III studies have met primary endpoint.

Tesaro conducted three Phase III studies (two in highly emetogenic chemotherapy or HEC and one in moderately emetogenic chemotherapy or MEC, and all met the primary endpoint of complete response (CR) in the delayed phase

Treatment-emergent adverse events (AEs) were similar between the rolapitant and control arms, and the most frequently AEs were fatigue, alopecia and constipation

phase are secondary endpoints. During the total phase, there were no emesis (78.7% vs. 65.3%; $p < 0.001$) and complete protection – defined as no emesis, no use of rescue medication and no significant nausea (62.0% vs. 53.2%, $p=0.001$). Treatment-emergent adverse events (AEs) were similar between the rolapitant and control arms, and the most frequently AEs were fatigue, alopecia and constipation.

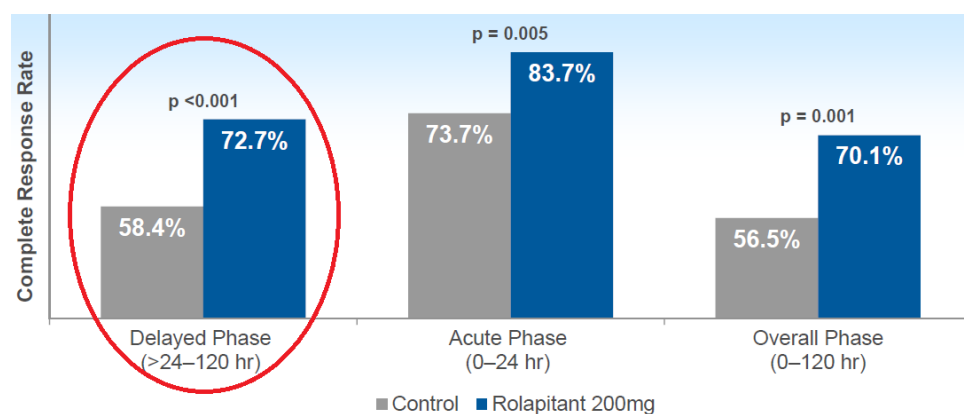
Figure 16: Rolapitant in MEC Phase III study met primary endpoint in delayed phase



Source: Tesaro company presentation

The HEC1 study results demonstrated that rolapitant exhibited a greater CR vs. control (72.7% vs. 58.4%, $p < 0.001$). The CR of total phase also exhibited statistically significant improvements (83.7% vs. 73.7%, $p=0.005$); and so were the CR of acute phase (70.1% vs. 56.5%, $p=0.001$) (Figure 17).

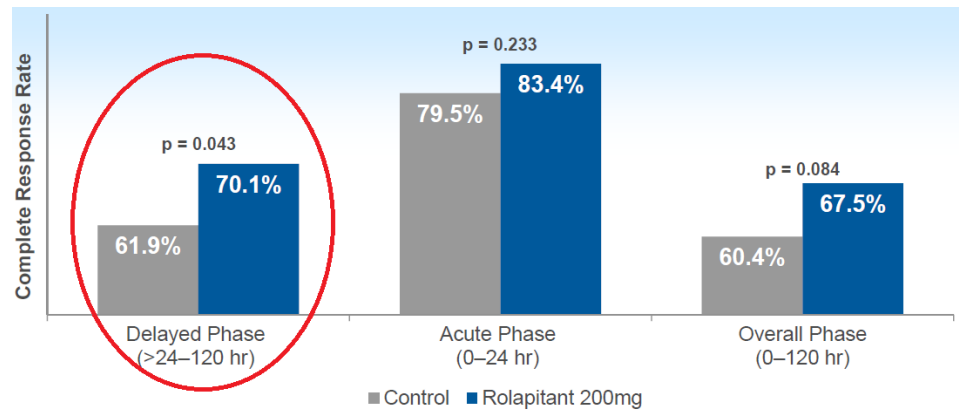
Figure 17: Rolapitant in cisplatin-based HEC1 Phase III study met primary endpoint



Source: Tesaro company presentation

The second HEC (HEC2) Phase III study results also demonstrated that rolapitant exhibited a greater CR vs. control (70.1% vs. 61.9%, $p = 0.043$). The CR of overall phase only exhibited positive improvements (67.5% vs. 60.4%, $p=0.084$); and so were the CR of acute phase (83.4% vs. 79.5%, $p=0.233$) (Figure 18). Both did not reach statistical significance.

Figure 18: Rolapitant in cisplatin-based HEC2 Phase III study met primary endpoint of delayed phase



Source: Tesaro company presentation

Rolapitant in CINV Phase III studies design. All three trials are randomized, double blind, parallel-group and active-controlled studies. The MEC study enrolled 1,369 patients, in which approximately half of whom were treated with anthracycline-based regimens for breast cancer. The primary endpoint of all three studies is complete response (CR) during the delayed phase following administration of chemotherapy. The HEC1 study enrolled 532 patients receiving cisplatin-based chemotherapy regimens at a dose equal to or greater than 60 mg/m². Patients in the control group received a 5-HT₃ receptor antagonist plus dexamethasone; while treatment group received 200 mg oral rolapitant plus control. The design of HEC2 study is similar to that of HEC1 except it enrolled 555 patients (Figure 19).

Figure 19: Rolapitant pivotal Phase III study designs

1	2	3
Phase 3 in MEC <i>Reported</i>	Phase 3 in HEC1 <i>Reported</i>	Phase 3 in HEC2 <i>Reported</i>
1,369 patients enrolled ~50% received A/C for breast cancer	532 patients enrolled All received cisplatin ≥ 60 mg/m ²	555 patients enrolled All receiving cisplatin ≥ 60mg/m ²
5-HT ₃ RA + dexamethasone	5-HT ₃ RA + dexamethasone	5-HT ₃ RA + dexamethasone
vs.	vs.	vs.
200mg rolapitant + 5-HT ₃ RA + dexamethasone	200mg rolapitant + 5-HT ₃ RA + dexamethasone	200mg rolapitant + 5-HT ₃ RA + dexamethasone
Endpoints	<ul style="list-style-type: none"> Primary: <i>Delayed</i> complete response (CR) in the 24-120 hr. period after chemotherapy Statistical plan required hierarchical analysis of the key secondary endpoints acute CR (0 to 24 hrs.) and overall CR (0 to 120 hrs.), and pre-specified adjustment for multiplicity for secondary endpoints 	

Source: Tesaro company presentation

For the IV formulation, Tesaro recently (2Q15) completed and reported results of a clinical study, indicating that 185 mg dose of IV rolapitant is bioequivalent to that of a 200 mg dose of oral rolapitant.

PDUFA date for oral rolapitant in CINV is scheduled on September 5, 2015.

Should the drug be granted approval, Tesaro plans to launch the product in 4Q15. We also estimate that the IV rolapitant in CINV could potentially receive approval in 4Q16 with launch shortly thereafter.

CINV can be broadly categorized as acute (occurring within 24 hours of therapy), and delayed (persisting for 6–7 days post therapy).

Anti-CINV therapies could be categorized into three types: neurokinin-1 (NK1) receptor antagonists, 5-hydroxytryptamine (5-HT₃) receptor antagonists and glucocorticoids.

Emend is the dominant NK1 receptor antagonist and the drug has generated ~\$550 MM sales in 2014. The patent of oral Emend is expected to expire in 2015; and on IV Emend in 2019.

Next step. Tesaro filed an NDA for oral rolapitant in CINV in September 2014 and the PDUFA date is scheduled on September 5, 2015. Should the drug be granted approval, Tesaro plans to launch the product in 4Q15. We also estimate that the IV rolapitant in CINV could potentially receive approval in 4Q16 with launch shortly thereafter.

Chemotherapy-induced nausea and vomiting (CINV) background. Nausea and vomiting are the common and most feared side effects of chemotherapy. It is caused by autonomic nervous system and multistep reflex driven by the activated neurotransmitter receptors located on the CNS and GI tract from serotonin (5-HT₃), and substance P that stimulated by chemotherapy. CINV can be broadly categorized as acute (occurring within 24 hours of therapy), and delayed (persisting for 6–7 days post therapy). Chemotherapeutic regimens can be classified as having high (HEC), moderate (MEC), low (10%-30%), or minimal (<10%) risk of emetogenicity. HEC defined as with 60% to >90% of frequency of emesis, and the causing chemotherapeutic agents include melphalan, dacarbazine, cisplatin, cyclophosphamide and AC (doxorubicin or epirubicin with cyclophosphamide). MEC defined as with 30% to 60% of frequency of emesis, and the causing chemotherapeutic agents include idarubicin, oxaliplatin, doxorubicin, ifosfamide and mitoxantrone.

Anti-CINV therapies could be categorized into three types: neurokinin-1 (NK1) receptor antagonists, 5-hydroxytryptamine (5-HT₃) receptor antagonists and glucocorticoids. Leading drugs in the 5-HT₃ receptor antagonists include Aloxi (palonosetron HCl), Zofran (ondansetron HCl) and Anzemet (dolasetron mesylate) and some of them already went generic. The leading drug in the NK1 receptor antagonists is Emend (aprepitant) from Merck.

Market dynamics Emend is the dominant NK1 receptor antagonist and the drug has generated ~\$550 MM sales in 2014. The patent on oral Emend is expected to expire in 2015; and on IV Emend in 2019. The majority (possibly >70%) of Emend revenues were generated from the IV formulation given the high prior authorization required by insurance companies for oral Emend in the U.S. In Europe, the pattern is reversed as more oral form was sold. Aloxi (sold in the U.S. by Eisai and developed by Helsinn) annual sales over the last few years were hovered around \$400+MM (\$436MM, \$442MM, \$428MM and \$453MM from 2011 to 2014). Helsinn recently (January 2015) reached a settlement with Sandoz for IV Aloxi and not to allow the generic version to be marketed in the U.S. until September 30, 2018. Eisai/Helsinn has launched Akynzeo (a fixed dose combination of netupitant and palonosetron) after the U.S. (October 2014) and Europe (June 2015) approvals. The potential approval of IV Akynzeo could be a few years later. Figure 20 illustrates a comparison among several major NK1 receptor antagonist containing anti-CINV drugs.

Market model assumptions: We anticipate oral rolapitant is likely to receive approval at the PDUFA date and Tesaro will launch the product starting in 4Q15. Given Tesaro senior management (led by CEO Leon Moulder Jr.) has significant experience and has successfully launched an anti-CINV drug (Aloxi

at MGI pharma), we believe the rolapitant commercialization could be meaningfully de-risked. We believe the potential approval of IV rolapitant in late 2016 would be critical for the commercial outlook of the franchise since the IV anti-CINV medications account for majority of the use in the U.S. We also view IV Emend patent expiration in 2019 could also afford rolapitant an opportunity to further gain greater market shares. We believe it is in rolapitant’s favor that its IV form could reach market a few years ahead of the IV Akynzeo.

Figure 20: Comparison among several leading anti-CINV agents

Product / product candidate	Developer	Mechanism of action	Status	Single dose oral	Single dose IV	No CYP 3A4 DDI Potential	Potential to Prevent nausea
Rolapitant	Tesaro	NK1 receptor antagonist	NDA filed PDUFA Sep. 5, '15	+	+	+	+
Emend (aprepitant oral & fosaprepitant IV)	Merck	NK1 receptor antagonist	Marketed Oral 3-day: 2003 IV 150mg: 2010	3-day oral	+	-	-
Akynzeo (Fixed dose netupitant-palonosetron)	Eisai/Helsinn/Chugai	NK1 + 5-HT ₃ receptor antagonist	Marketed Approved: 10/13/14	+	-	-	Unknown

Source: Tesaro company presentation and Laidlaw and co, equity research

We also assume a potential royalty rate of 14% payable to OPK. As such, we estimate OPK could receive ~\$50+MM royalty payments annually during drug’s peak sales.

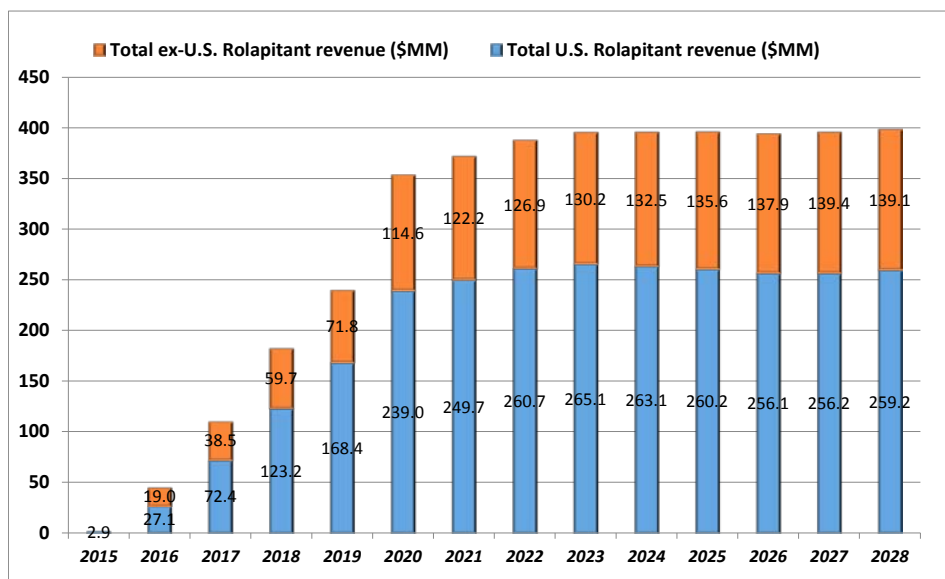
In our rolapitant market model, we assume total global peak sales reaching ~\$400MM with the U.S. accounts for \$260MM and Europe with \$130+MM. We also assume a potential royalty rate of 14% payable to OPK. As such, we estimate OPK could receive ~\$50+MM royalty payments annually during drug’s peak sales.

Figure 21a: Rolapitant in CINV revenue model

Rolapitant in CINV Revenue Model														
	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Incidences of cancer in the U.S.	1,658,370	1,676,612	1,695,055	1,713,700	1,732,551	1,751,609	1,770,877	1,790,357	1,810,050	1,829,961	1,850,091	1,870,442	1,891,016	1,911,818
Cancer patients received chemotherapy	1,492,533	1,508,951	1,525,549	1,542,330	1,559,296	1,576,448	1,593,789	1,611,321	1,629,045	1,646,965	1,665,082	1,683,397	1,701,915	1,720,636
Chemo-treated patients experiencing CINV	1,119,400	1,131,713	1,144,162	1,156,748	1,169,472	1,182,336	1,195,342	1,208,491	1,221,784	1,235,224	1,248,811	1,262,548	1,276,436	1,290,477
Total CINV in all cancer doses	5,037,299	5,092,709	5,148,729	5,205,365	5,262,624	5,320,513	5,379,039	5,438,208	5,498,028	5,558,507	5,619,650	5,681,466	5,743,962	5,807,146
Highly emetogenic chemotherapy (HEC)	755,595	763,906	772,309	780,805	789,394	798,077	806,856	815,731	824,704	833,776	842,948	852,220	861,594	871,072
Moderately emetogenic chemotherapy (MEC)	4,281,704	4,328,803	4,376,420	4,424,560	4,473,230	4,522,436	4,572,183	4,622,477	4,673,324	4,724,731	4,776,703	4,829,246	4,882,368	4,936,074
% of HEC receive Rolapitant	1.0%	6.0%	19.0%	35.0%	50.0%	70.0%	66.0%	62.0%	60.0%	58.0%	55.0%	52.0%	51.0%	50.0%
Cancer patients received chemotherapy	7,556	45,834	146,739	273,282	394,697	558,654	3,215,552	505,753	494,823	483,590	463,621	443,154	439,413	435,536
Rolapitant-WAC (\$)	300	305	309	314	318	323	328	333	338	343	348	353	359	364
Rolapitant-HEC revenue (\$MM)	2.3	14.0	45.4	85.7	125.7	180.5	174.7	168.4	167.2	165.9	161.4	156.6	157.6	158.6
% of MEC receive Rolapitant	0.1%	1.0%	2.0%	2.7%	3.0%	4.0%	5.0%	6.0%	6.2%	6.0%	5.9%	5.8%	5.6%	5.6%
Cancer patients received chemotherapy	2,141	43,288	87,528	119,463	134,197	180,897	228,609	277,349	289,746	283,484	283,736	281,545	274,877	276,420
Rolapitant-MEC revenue (\$MM)	0.6	13.2	27.1	37.5	42.7	58.5	75.0	92.3	97.9	97.2	98.8	99.5	98.6	100.6
Total Rolapitant-treated doses	9,697	89,122	234,267	392,745	528,894	739,551	761,134	783,102	784,569	767,074	747,357	724,699	714,290	711,956
Total U.S. Rolapitant revenue (\$MM)	2.9	27.1	72.4	123.2	168.4	239.0	249.7	260.7	265.1	263.1	260.2	256.1	256.2	259.2
Incidences of cancer in Europe	3,450,370	3,474,523	3,498,844	3,523,336	3,548,000	3,572,836	3,597,845	3,623,030	3,648,391	3,673,930	3,699,648	3,725,545	3,751,624	3,777,885
Cancer patients received chemotherapy	3,105,333	3,127,070	3,148,960	3,171,003	3,193,200	3,215,552	3,238,061	3,260,727	3,283,552	3,306,537	3,329,683	3,352,991	3,376,462	3,400,097
Chemo-treated patients experiencing CINV	2,329,000	2,345,303	2,361,720	2,378,252	2,394,900	2,411,664	2,428,546	2,445,545	2,462,664	2,479,903	2,497,262	2,514,743	2,532,346	2,550,073
Total CINV in all cancer doses	9,315,999	9,381,211	9,446,879	9,513,008	9,579,599	9,646,656	9,714,182	9,782,182	9,850,657	9,919,612	9,989,049	10,058,972	10,129,385	10,200,291
Highly emetogenic chemotherapy (HEC)	1,397,400	1,407,182	1,417,032	1,426,951	1,436,940	1,446,998	1,457,127	1,467,327	1,477,599	1,487,942	1,498,357	1,508,846	1,519,408	1,530,044
Moderately emetogenic chemotherapy (MEC)	7,918,599	7,974,029	8,029,848	8,086,056	8,142,659	8,199,657	8,257,055	8,314,854	8,373,058	8,431,670	8,490,692	8,550,126	8,609,977	8,670,247
% of HEC receive Rolapitant	1.0%	2.0%	5.0%	7.0%	15.0%	14.0%	13.7%	13.5%	13.5%	13.5%	13.5%	13.5%	13.5%	13.3%
Cancer patients received chemotherapy	14,072	28,341	71,348	100,586	217,050	203,998	201,024	199,476	200,872	202,728	204,298	205,120	203,496	
Rolapitant-WAC (\$)	200	202	204	206	208	210	212	214	217	219	221	223	225	228
Rolapitant-HEC revenue (\$MM)	2.8	5.8	14.7	20.9	45.6	43.3	43.1	43.2	43.9	44.8	45.6	46.2	46.3	46.3
% of MEC receive Rolapitant	1.0%	2.0%	2.7%	3.0%	4.0%	4.5%	4.7%	4.8%	4.8%	4.8%	4.8%	4.8%	4.8%	4.7%
Cancer patients received chemotherapy	79,740	160,597	218,324	244,280	327,986	371,567	390,798	401,907	404,720	410,949	413,826	413,279	407,502	
Rolapitant-MEC revenue (\$MM)	16.1	32.8	45.0	50.8	68.9	78.9	83.8	87.0	88.5	90.8	92.3	93.1	92.8	
Total Rolapitant-treated doses	93,812	188,938	289,671	344,866	545,036	575,565	591,822	601,383	605,592	613,677	618,124	618,399	610,997	
Total ex-U.S. Rolapitant revenue (\$MM)	19.0	38.5	59.7	71.8	114.6	122.2	126.9	130.2	132.5	135.6	137.9	139.4	139.1	
Total WW Rolapitant revenue (\$MM)	2.9	46.1	111.0	182.9	240.2	353.6	371.9	387.6	395.4	395.6	395.8	394.0	395.6	398.3
Potential royalties paid to OPK (\$MM)	0.4	6.5	15.5	25.6	33.6	49.5	52.1	54.3	55.4	55.4	55.4	55.2	55.4	55.8

Source: Laidlaw & Company estimates

Figure 21b: Rolapitant in CINV revenue model



Source: Laidlaw & Company estimates

Long-acting growth hormone in growth hormone deficiency (GHD) could have very large market potential as the first-to-market long acting hGH

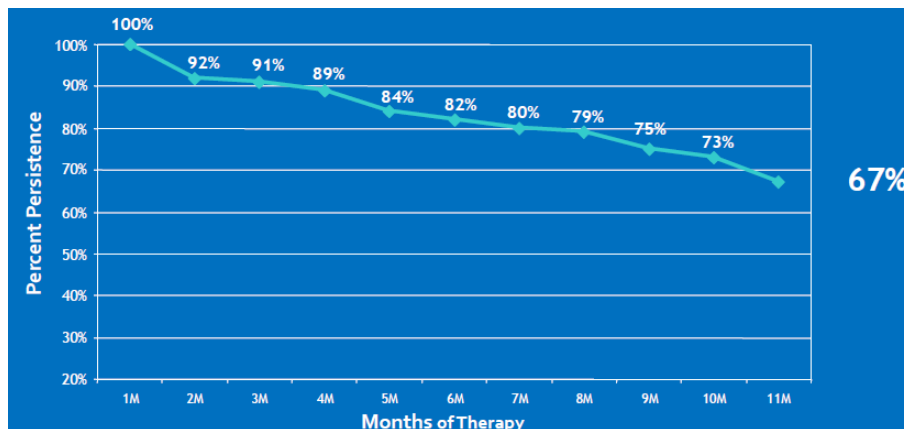
The leading development of OPK’s Biologics division is MOD-4023 (hGH-CTP), a long-acting human growth hormone (hGH) modified by the company’s CTP technology. MOD-4023 is designed as a once-weekly dosed hGH for a potential treatment in pediatric and adult growth hormone deficiency (GHD). All marketed hGHs are dosed daily. Given the treatment duration for both adult and pediatric GHD are rather long (~10 years) and, therefore the continued daily administration of hGH has resulted in low compliance. For example, the compliance of taking hGH daily in pediatric GHD has consistently reduced over time (Figure 22). By 11th month of treatment, the compliance has declined to ~67%. In addition, the compliance decline has consistently worsened over time: for patients undertaking hGH therapy for six years, only 19% of patients still administer the drug daily as reported in 1999 (Figure 23).

The major problem of non-compliance for hGH treatment is that the therapeutic effect could be significantly impaired even with a patient only missing injections for few days. Figure 24 illustrates that even missed between one and three doses of treatment per week (the medium group in Figure 24), the anticipated linear growth, measured by height velocity standard deviation score (HVSDS) over 6 to 8 months has materially reduced. Together, we believe improving compliance by reducing dosing frequency could be important not only enhance treatment efficacy but also could encourage many more patients to take hGH treatment.

The major problem of non-compliance for hGH treatment is that the therapeutic effect could be significantly impaired even with a patient only missing injections for few

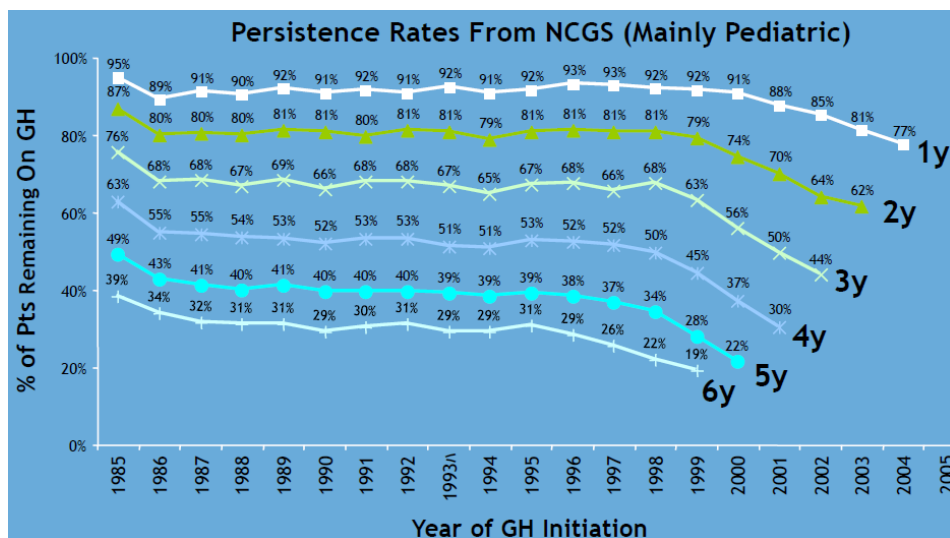
Improving compliance by reducing dosing frequency could be important not only enhance treatment efficacy but also could encourage many more patients to take hGH treatment

Figure 22: Compliance in children receiving Nutropin tends to reduce over time



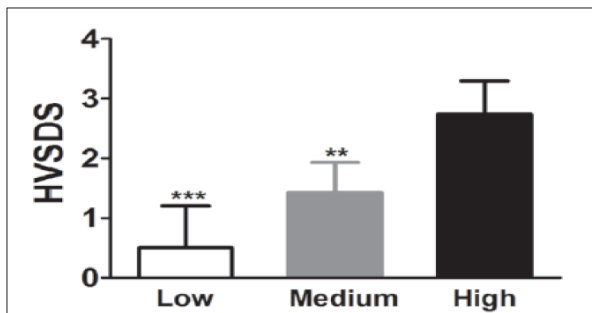
Source: Company presentation

Figure 23: Decline in compliance is steady over time



Source: Company presentation

Figure 24: Poor compliance leads to slower growth



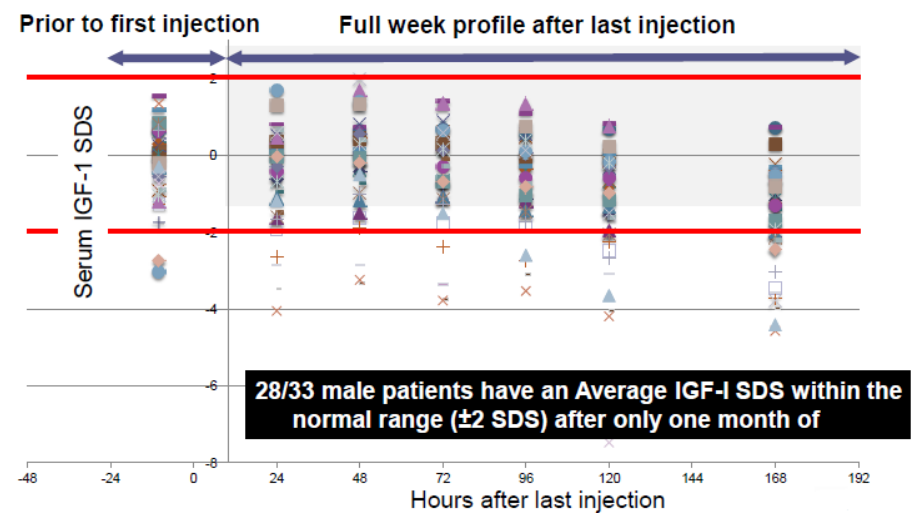
Source: Company presentation

MOD-4023 is initially developed by Prolor Biologics, and OPKO Health acquired Prolor in 3Q13 and continued its development.

MOD-4023 in adult GHD development. OPK conducted Phase II studies evaluating MOD-4023 in both adult and pediatric GHD. The positive MOD-4023 in GHD adult (GHDA) Phase II study results are encouraging and, we believe, they bode well for positive outcome from ongoing Phase III pivotal study. The MOD-4023 in GHDA Phase II study is divided into two stages: a 4-week dose finding stage followed by dose confirmatory stage. During the first stage, 28/33 male patients have exhibited average IGF-I SDS that were within the normal range (± 2 SDS) after one month of treatment (Figure 25). IGF-1 SDS or insulin-like growth factor (IGF)-1 standard deviation score profile is a standard method to measure the growth. GH regulates the production of IGF-I, and together, promote longitudinal growth.

During the first stage of Phase II studies, 28/33 male patients have exhibited average IGF-I SDS that were within the normal range (± 2 SDS) after one month of treatment

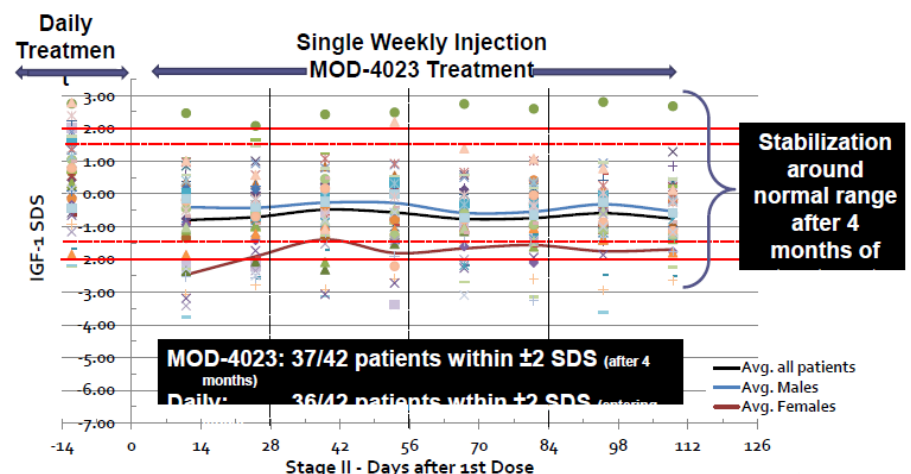
Figure 25: Positive stage I MOD-4023 in adult GHD Phase II study results



Source: Company presentation

In addition, during the extension study, MOD-4023 therapy exhibited effective maintenance of IGF-1 levels within normal range after four months of treatment (Figure 26).

Figure 26: Positive second stage MOD-4023 in adult GHD Phase II study results



Source: Company presentation

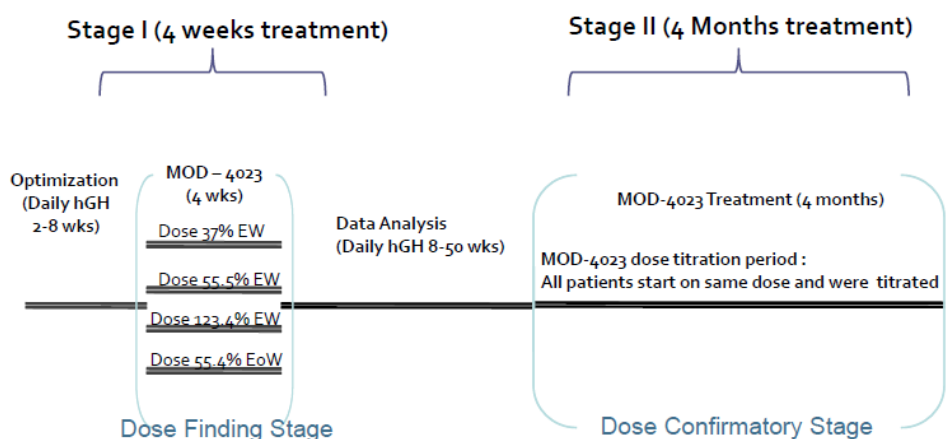
During the extension study, MOD-4023 therapy exhibited effective maintenance of IGF-1 levels within normal range after four months of treatment

Together, the study demonstrated that 1) single weekly injection of MOD-4023 can replace 7 consecutive daily GH injections; 2) only 50-65% of the cumulative weekly dose was required to maintain the majority of the patients within the normal range; and 3) good safety & tolerability profile and without unexpected AEs.

MOD-4023 in GHDA Phase II study design. It is a randomized, open-label, comparative dose finding study with objective to evaluate safety, tolerability, PK and PD of MOD-4023 in GHDA patients. The study expects to identify optimal dose and dosing regimen of MOD-4023 for the subsequent Phase III study on the basis of safety and PK/PD parameters after 1 and 4 months of treatment (Figure 27).

The study demonstrated that 1) single weekly injection of MOD-4023 can replace 7 consecutive daily GH injections; 2) only 50-65% of the cumulative weekly dose was required to maintain the majority of the patients within the normal range; and 3) good safety & tolerability profile and without unexpected AEs.

Figure 27: MOD-4023 in adult GHD Phase II study design



Source: Company presentation

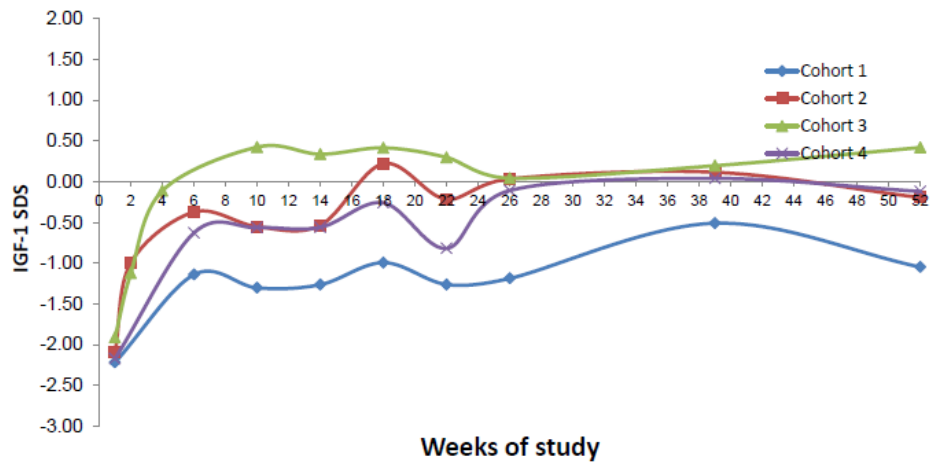
Ongoing development. The company commenced a Phase III study to evaluate the efficacy and safety of MOD-4023 in GHDA in mid-2013. It is a randomized, double-blind, placebo-controlled, 189-patient, and multicenter trial. The primary endpoint is change in trunk fat mass (FM) from baseline to week 26, measured by DXA. OPK reported in mid-2015 that the patient enrollment has completed and our discussion with management indicated that that the study could be completed in 3Q16 with top-line results anticipated shortly thereafter. As such, we estimate Pfizer might file a BLA in late 2016 with potential approval in 2H17. MOD-4023 in GHDA also received orphan drug designation in both the U.S. and Europe.

The Phase III study could be completed in 3Q16 with top-line results anticipated shortly thereafter. We estimate Pfizer might file a BLA in late 2016 with potential approval in 2H17.

MOD-4023 in pediatric GHD development. In addition to exploring treatment in adults, OPK also conducted a Phase II study evaluating MOD-4023 in pediatric GHD. The favorable results illustrated that the twelve months data confirm comparable response of MOD-4023 (of two higher doses) to daily Genotropin therapy. The outcomes are reflected by the similar twelve months IGF-1SDS (Figure 28) and IGFBP-3 (Figure 29) profile. Further, functional measurements, such as annual height velocity (HV) and HV SDS (Figure 30) also illustrated the same trend.

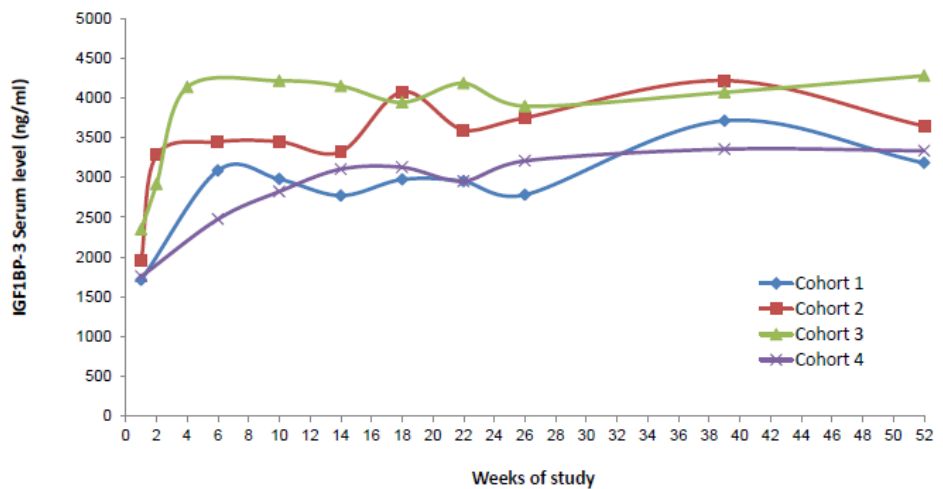
Figure 28: 45–100% of the wkly cumulative dose, IGF-I values comparable to daily GH injections (measured by IGF-1 SDS)

A Phase II study evaluating MOD-4023 in pediatric GHD showed favorable results that the twelve months data confirm comparable response of MOD-4023 (of two higher doses) to daily Genotropin therapy.



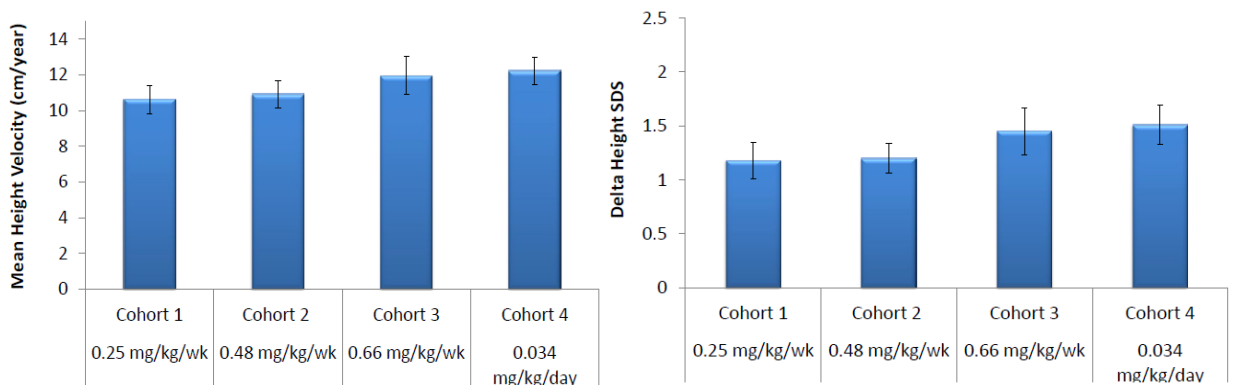
Source: Company presentation

Figure 29: 12 months IGFBP-3 level from MOD-4023 in pediatric GHD Phase II study



Source: Company presentation

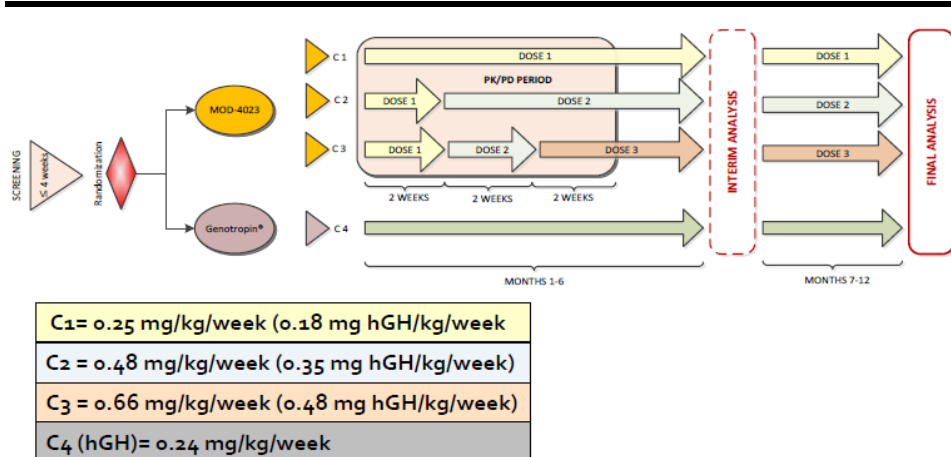
Figure 30: MOD-4023 in pediatric GHD Phase II study exhibited comparable function as Genotropin (HV, left; Δ HtSDS, right)



Source: Company presentation

MOD-4023 in pediatric GHD Phase II study design. It is a randomized, 56-patient, controlled Phase II study that evaluates three doses (0.25–0.66 mg/kg per week) of MOD-4023 vs. daily GH (34 µg/kg per day) with a 6-month interim and 12-month final analysis. The study expects to identify optimal dose and dosing regimen of MOD-4023 for the subsequent Phase III study on the basis of safety and PK/PD parameters (Figure 31).

Figure 31: MOD-4023 in pediatric GHD Phase II study design



Source: Company presentation

Upcoming development. Pfizer is developing a pen device to deliver MOD-4023 instead of syringe as many market analyses suggested it is a more favorable delivery device and could facilitate greater market penetration. Accordingly, OPK is scheduled to start a MOD-4023 in pediatric GHD Phase III study with possible commencement in 1H16 (possibly in mid-2016). Based on this timeline and that the pediatric study is relatively small and with shorter duration, we estimate the study could complete with top-line result reporting in 2018 and possible approval and product launch in 2019.

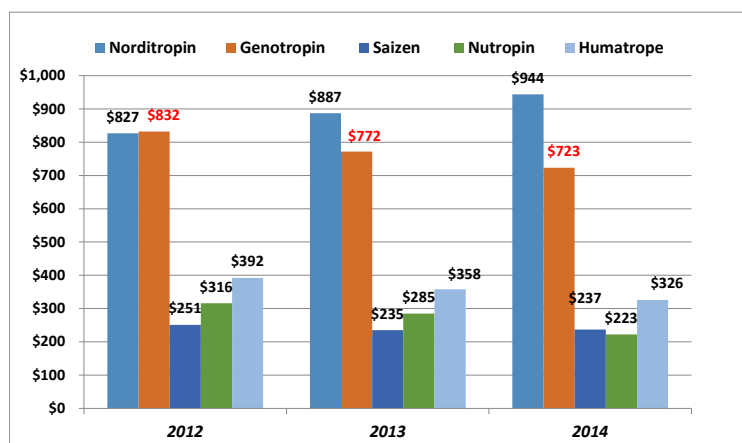
Pfizer partnership. OPK entered into a partnership with Pfizer in December 2014 for the development and commercialization of MOD-4023 in adult and pediatric GHD and other indications, such as children born small for gestational age (SGA). The terms of the deal include a \$295MM upfront payment and milestone payments of \$275MM. OPK is also entitled to receive double digit royalty payments associated with the commercialization of MOD-4023 for GHDA. After the launch of MOD-4023 in pediatric GHD, the royalty payment will transition to a profit sharing model based on regional, tiered gross profit for both MOD-4023 and Pfizer’s Genotropin. The details of profit sharing were not revealed. OPK will responsible for clinical development of MOD-4023 in pediatric and adult GHD as well as SGA; while Pfizer is responsible for clinical developments of other indications and commercialization.

Our take on MOD-4023 outlook. We are bullish on the potential success of MOD-4023 in GDH and other growth hormone related indications based on: 1) clinical data reported so far are very encouraging; 2) the Pfizer deal provides a strong validation given the company has chances to review all other long-acting

OPK is scheduled to start a Phase III MOD-4023 in pediatric GHD Phase III study with possible commencement in 1H16 (possibly in mid-2016). We estimate the study could complete with top-line result reporting in 2018 and possible approval and product launch in 2019

hGH programs in development, and a robust long-acting hGH is critical for the extension and expansion of its Genotropin franchise especially the product has experienced sales declines over the last few years (Figure 32); and 3) MOD-4023 is likely to be the first long acting human growth hormone reach the market. Given the potential first-mover advantage and substantial benefit of long acting hGH, MOD-4023 could potentially gain and possibly retain greater market share and reverse the declining sales trend of the Genotropin franchise.

Figure 32: Recent hGH sales trend



MOD-4023 is likely to be the first long acting human growth hormone reach the market.

Source: Laidlaw and co. equity research

Competitive landscape of long-acting hGH in GHD. There are a fewer than a dozen programs in development for long-acting hGH (Figure 33). In addition to MOD-4023, we believe several more prominent programs are NNCO195-0092 (Novo Nordisk), VRS-317 (Versartis), ACP-001 (Ascendis Pharma) and TV-1106 (Teva).

Figure 33: Long-acting human growth hormone development pipeline

Product Name	Company	Ticker	Clinical Stage		Methodology
			Adult	Pediatric	
LBO03002	LG Life Sciences Ltd.	LGLS	Approved in Europe		Depot
NNCO195-0092	Novo Nordisk A/S	NOVOB	Phase III	Phase II	Prodrug
MOD-4023	Opko Health / Pfizer	OPK / PFE	Phase III	Phase II	GH fusion protein
TV-1106	Teva Pharmaceutical	TEVA	Phase II and III		GH fusion protein
VRS-317	Versartis, Inc.	VSAR	Phase III	Phase II	GH fusion protein
ACP-001 / TransCon	Ascendis Pharma A/S	ASND	Phase II	Phase II	Prodrug
GX-H9	Genexine Co, Ltd. / Handok	095700 / 002390 (KOSDAQ)	Phase II		GH fusion protein
LAPSmGH / HM10560A	Hamni Pharma Co. Ltd.	128940 (KOSDAQ)	Phase II		GH fusion protein
BBT-031	Bolder BioTechnology		Pre-clinical		Pegylated
CP-016	Critical Pharmaceuticals		Pre-clinical		Pegylated
Profuse GH	Asterion Ltd.		Pre-clinical		GH fusion protein
Jintrolong	GeneScience Pharmaceuticals			Marketed in China	Pegylated
ARX201	Ambix Inc.	AMBX	Termination		Pegylated
ALTU-238	Ajinomoto Co.	2802 (Tokyo)	Termination		GH fusion protein
NNC126-0083	Novo Nordisk A/S	NOVOB	Termination		Pegylated
Nutropin Depot	Genetech / Alkermes	DNA / ALKS	Termination		Depot
PEG-GH PHA-794428	Pfizer	PFE	Termination		Pegylated

Source: Laidlaw and co. equity research and Hoybye, C., Growth Hormone & IGF Research, 2015, 25:

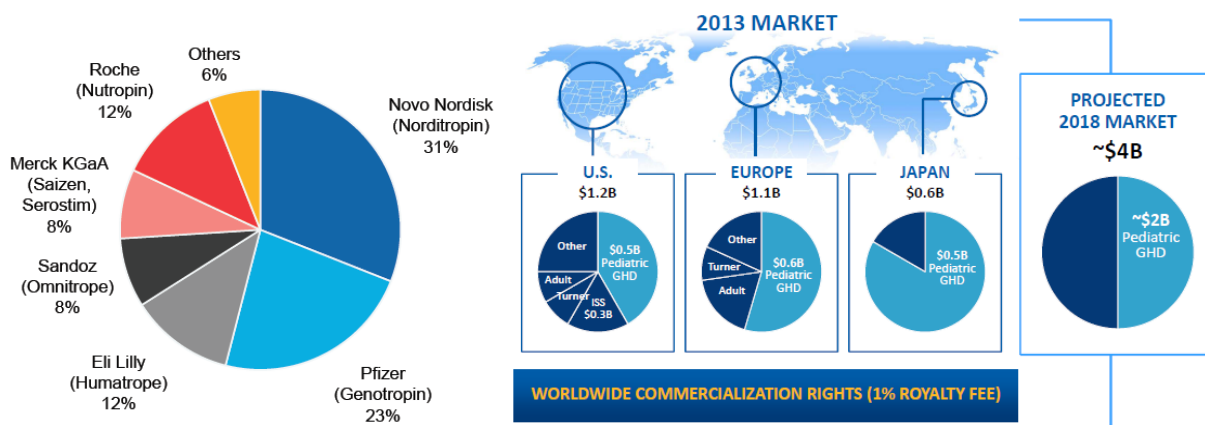
NNCO195-0092 or NN8640 (Novo Nordisk) It is a GH with single-point mutation plus the potential binding to circulating albumin via non-covalent linkage as once weekly long-acting hGH for the objective to reduce the clearance of the drug and prolongs the absorption rate. Phase III study that evaluates NNCO195-0092 in GHDA (REAL1, n=280 and REAL2, n=90) are ongoing. We believe NNCO195-0092 is an important part of product life cycle management for its Norditropin franchise. According to the development timeline (study started in 3Q14 and 1Q15, respectively), we estimate that MOD-4023 could potentially reach market before NN8640. NN8640 possibly could also commence a Phase III study in pediatric patients in 2016.

TV-1106 (Teva) It is a long-acting GH with human serum albumin (HSA) fused into its N-terminus. TV-1106 is administered weekly and the product is produced using a yeast system. A Phase III study in GHDA (n=180) and a Phase II study in pediatric GHD (n=60) are underway.

VRS-317 (Versartis) By combining GH and XTEN, long chains of natural hydrophilic amino acids, VRS-317 could extend the half-life of GH by increasing the hydrodynamic size of GH and delaying receptor mediated clearance through a reduction in receptor binding. VRS-317 is designed to be administered once monthly. A Phase III study (n=136) that evaluates VRS-317 in pediatric GHD; a Phase II/III trial in pediatric GHD in Japan; and a Phase II study in GHDA study are ongoing.

ACP-001 (Ascendis Pharma) It is a prodrug that releases unmodified GH by undergoing non-enzymatic cleavage under physiological pH and temperature. ACP-001 is designed for once-weekly subcutaneous injections. The company in July 2015 reported promising ACP-001 in pediatric GHD Phase II study results. The study demonstrated that after six months of treatment, three different doses of ACP-001 (0.14; 0.21; and 0.30 mg hGH/kg/week) achieved mean annualized height velocities between 11.9 cm and 13.9 cm; which is similar to 11.6 cm achieved by daily injections of Genotropin at a 0.21 mg/kg/week. Ascendis is scheduled to start a Phase III study in mid-2016.

Figure 34: Global hGH market is dominated with a handful of players with pediatric GHD accounts for half



Source: Versartis company presentation

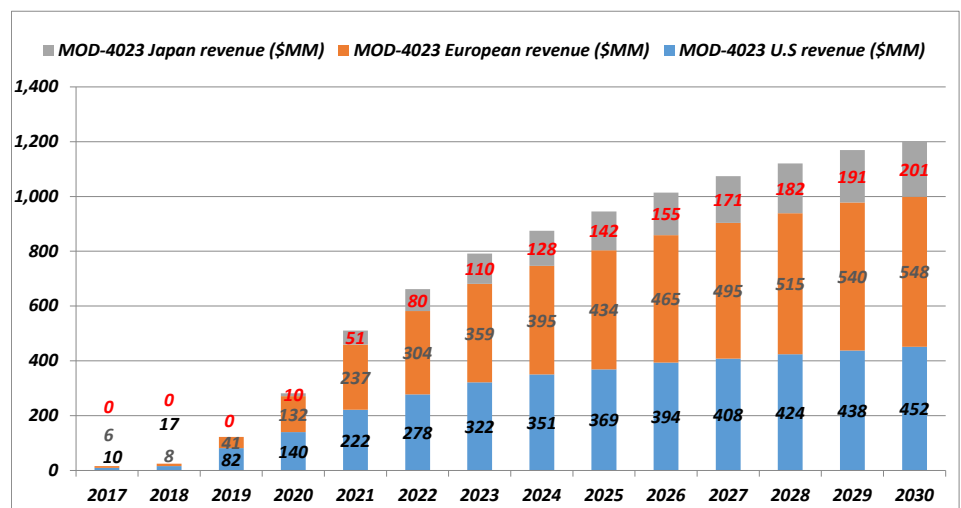
MOD-4023 market model assumptions: The hGH market has reached \$3.5 billion in 2014 and with very modest growth. Long-acting hGH could potentially expand the entire hGH market by improving the compliance and attracting more patients taking treatment. The current market landscape is dominated by a handful of products (Figure 34), and pediatric GHD accounts for near half the current sales. In our MOD-4023 market model, we assume approval for adult GHD in 2H17 and product launch shortly thereafter. We also assume potential approval and product launch in pediatric GHD in 2019. Our revenue model suggests that the global sales of MOD-4023 could reach \$1.2 billion. By the out years, we believe long acting hGH could be the dominant product in the overall hGH market with potentially greater than 80% share. With the first mover advantage, we believe MOD-4023 could gain and maintain a substantial market share.

Figure 35a: MOD-4023 in growth hormone deficiency revenue model

Long-acting human Growth Hormone Revenue Model														
	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Adult GHD patients in the U.S.	50,100	50,150	50,200	50,251	50,301	50,351	50,401	50,452	50,502	50,553	50,603	50,654	50,705	50,755
% of penetration	1%	1%	3%	4%	5%	6%	6%	7%	7%	7%	7%	7%	7%	7%
MOD-4023 treated patients	301	502	1,506	2,211	2,666	3,021	3,175	3,279	3,283	3,387	3,492	3,596	3,651	3,654
Annual costs -U.S. (\$)	32,278	32,936	33,608	34,294	34,993	35,707	36,436	37,179	37,937	38,711	39,501	40,307	41,129	41,968
MOD-4023 in adult GHD U.S revenue (\$MM)	<u>10</u>	<u>17</u>	<u>51</u>	<u>76</u>	<u>93</u>	<u>108</u>	<u>116</u>	<u>122</u>	<u>125</u>	<u>131</u>	<u>138</u>	<u>145</u>	<u>150</u>	<u>153</u>
Adult GHD patients in Europe	60,120	60,180	60,240	60,301	60,361	60,421	60,482	60,542	60,603	60,663	60,724	60,785	60,845	60,906
% of penetration	0%	1%	2%	4%	5%	6%	6%	7%	7%	8%	9%	9%	9%	9%
MOD-4023 treated patients	240	301	904	2,412	3,018	3,625	3,871	4,056	4,424	4,792	5,162	5,288	5,598	5,482
Annual costs - EU (\$)	26,880	27,148	27,420	27,694	27,971	28,251	28,533	28,819	29,107	29,398	29,692	29,989	30,289	30,592
MOD-4023 in adult GHD EU revenue (\$MM)	<u>8</u>	<u>8</u>	<u>25</u>	<u>67</u>	<u>84</u>	<u>102</u>	<u>110</u>	<u>117</u>	<u>129</u>	<u>141</u>	<u>153</u>	<u>159</u>	<u>170</u>	<u>168</u>
Adult GHD patients in Japan	10,020	10,030	10,040	10,050	10,060	10,070	10,080	10,090	10,100	10,110	10,120	10,130	10,140	10,150
% of penetration				1%	3%	4%	5%	6%	6%	7%	7%	8%	8%	8%
MOD-4023 treated patients				101	302	443	504	575	636	698	739	760	761	761
Annual costs - Japan (\$)	29,093	29,384	29,678	29,975	30,275	30,577	30,883	31,192	31,504	31,819	32,137	32,458	32,783	33,111
MOD-4023 in adult GHD U.S revenue (\$MM)				<u>3</u>	<u>9</u>	<u>14</u>	<u>16</u>	<u>18</u>	<u>20</u>	<u>22</u>	<u>24</u>	<u>25</u>	<u>25</u>	<u>25</u>
Global MOD-4023 adult GHD revenue (\$MM)	<u>16</u>	<u>25</u>	<u>75</u>	<u>146</u>	<u>187</u>	<u>224</u>	<u>242</u>	<u>257</u>	<u>273</u>	<u>294</u>	<u>315</u>	<u>328</u>	<u>345</u>	<u>346</u>
Pediatric GHD patients in the U.S.	18,504	18,596	18,689	18,783	18,877	18,971	19,066	19,161	19,257	19,353	19,450	19,547	19,645	19,743
% of penetration	5%	10%	17%	21%	24%	26%	27%	28%	28%	28%	28%	28%	28%	28%
MOD-4023 treated patients	934	1,878	3,209	3,984	4,576	4,982	5,199	5,419	5,446	5,473	5,501	5,528	5,528	5,528
Annual costs -U.S. (\$)	32,278	32,936	33,608	34,294	34,993	35,707	36,436	37,179	37,937	38,711	39,501	40,307	41,129	41,968
MOD-4023 in pediatric GHD U.S revenue (\$MM)			<u>31</u>	<u>64</u>	<u>112</u>	<u>142</u>	<u>167</u>	<u>185</u>	<u>197</u>	<u>210</u>	<u>215</u>	<u>221</u>	<u>226</u>	<u>232</u>
Pediatric GHD patients in Europe	19,190	19,286	19,383	19,480	19,577	19,675	19,773	19,872	19,972	20,072	20,172	20,273	20,374	20,476
% of penetration	3%	12%	19%	23%	26%	29%	30%	31%	31%	33%	34%	35%	35%	35%
MOD-4023 treated patients	581	2,338	3,720	4,525	5,141	5,564	5,991	6,282	6,616	6,893	7,131	7,167	7,167	7,167
Annual costs - EU (\$)	26,880	27,148	27,420	27,694	27,971	28,251	28,533	28,819	29,107	29,398	29,692	29,989	30,289	30,592
MOD-4023 in pediatric GHD EU revenue (\$MM)			<u>16</u>	<u>65</u>	<u>104</u>	<u>128</u>	<u>147</u>	<u>160</u>	<u>174</u>	<u>185</u>	<u>196</u>	<u>207</u>	<u>216</u>	<u>219</u>
Pediatric GHD patients in Japan	8,080	8,121	8,161	8,202	8,243	8,284	8,326	8,367	8,409	8,451	8,493	8,536	8,579	8,621
% of penetration				3%	9%	14%	19%	22%	24%	26%	28%	29%	30%	32%
MOD-4023 treated patients	246	742	1,160	1,582	1,841	2,052	2,223	2,378	2,510	2,608	2,793	2,932	3,028	3,111
Annual costs - Japan (\$)	29,093	29,384	29,678	29,975	30,275	30,577	30,883	31,192	31,504	31,819	32,137	32,458	32,783	33,111
MOD-4023 in pediatric GHD U.S revenue (\$MM)				<u>7</u>	<u>22</u>	<u>35</u>	<u>49</u>	<u>57</u>	<u>65</u>	<u>71</u>	<u>76</u>	<u>81</u>	<u>85</u>	<u>92</u>
Global MOD-4023 pediatric GHD revenue (\$MM)			<u>47</u>	<u>137</u>	<u>239</u>	<u>306</u>	<u>362</u>	<u>403</u>	<u>436</u>	<u>465</u>	<u>488</u>	<u>509</u>	<u>528</u>	<u>544</u>
MOD-4023 treated patients in other GHD in the U.S.	470	780	1,080	1,180	1,256	1,366	1,400	1,447	1,498	1,580	1,647	1,711	1,780	1,850
Annual costs -U.S. (\$)	32,278	32,936	33,608	34,294	34,993	35,707	36,436	37,179	37,937	38,711	39,501	40,307	41,129	41,968
MOD-4023 in other GHD U.S revenue (\$MM)				<u>16</u>	<u>28</u>	<u>39</u>	<u>44</u>	<u>48</u>	<u>53</u>	<u>55</u>	<u>58</u>	<u>62</u>	<u>66</u>	<u>66</u>
MOD-4023 treated patients in other GHD in EU	1,750	2,610	3,580	4,100	4,500	4,750	4,890	4,979	5,110	5,250	5,390	5,530	5,670	5,810
Annual costs - EU (\$)	26,880	27,148	27,420	27,694	27,971	28,251	28,533	28,819	29,107	29,398	29,692	29,989	30,289	30,592
MOD-4023 in other GHD EU revenue (\$MM)				<u>49</u>	<u>74</u>	<u>102</u>	<u>118</u>	<u>131</u>	<u>140</u>	<u>145</u>	<u>149</u>	<u>155</u>	<u>161</u>	<u>161</u>
MOD-4023 treated patients in other GHD in Japan	650	1,000	1,480	1,700	1,810	1,950	2,199	2,332	2,450	2,510	2,608	2,793	2,932	3,111
Annual costs - Japan (\$)	29,093	29,384	29,678	29,975	30,275	30,577	30,883	31,192	31,504	31,819	32,137	32,458	32,783	33,111
MOD-4023 in other GHD Japan revenue (\$MM)				<u>20</u>	<u>31</u>	<u>46</u>	<u>53</u>	<u>57</u>	<u>62</u>	<u>71</u>	<u>76</u>	<u>80</u>	<u>83</u>	<u>83</u>
Global MOD-4023 other GHD revenue (\$MM)			<u>0</u>	<u>0</u>	<u>85</u>	<u>132</u>	<u>187</u>	<u>215</u>	<u>236</u>	<u>255</u>	<u>271</u>	<u>283</u>	<u>297</u>	<u>310</u>
Global MOD-4023 revenue (\$MM)	<u>16</u>	<u>25</u>	<u>123</u>	<u>282</u>	<u>511</u>	<u>662</u>	<u>791</u>	<u>875</u>	<u>945</u>	<u>1,014</u>	<u>1,074</u>	<u>1,120</u>	<u>1,169</u>	<u>1,200</u>
MOD-4023 U.S revenue (\$MM)	<u>10</u>	<u>17</u>	<u>82</u>	<u>140</u>	<u>222</u>	<u>278</u>	<u>322</u>	<u>351</u>	<u>369</u>	<u>394</u>	<u>408</u>	<u>424</u>	<u>438</u>	<u>452</u>
MOD-4023 European revenue (\$MM)	<u>6</u>	<u>8</u>	<u>41</u>	<u>132</u>	<u>237</u>	<u>304</u>	<u>359</u>	<u>395</u>	<u>434</u>	<u>465</u>	<u>495</u>	<u>515</u>	<u>540</u>	<u>548</u>
MOD-4023 Japan revenue (\$MM)	<u>0</u>	<u>0</u>	<u>0</u>	<u>10</u>	<u>51</u>	<u>80</u>	<u>110</u>	<u>128</u>	<u>142</u>	<u>155</u>	<u>171</u>	<u>182</u>	<u>191</u>	<u>201</u>

Source: Laidlaw & Company estimates

Figure 35b: MOD-4023 in growth hormone deficiency revenue model



Source: Laidlaw & Company estimates

MOD-4023 royalty and profit-sharing revenue to OPK. We assume market launch of MOD-4023 in pediatric GHD could start in 2019 with profit-sharing kicking in. We assume COGS of 11% and profit sharing of 25% based on operating profits. We also assume the product switch from Genotropin to once weekly MOD-4023 takes three years to complete with minimum level of daily Genotropin available going forward to serve small percentages of patients.

Figure 36: MOD-4023 revenue payable to OPK

	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Global MOD-4023 revenue (\$MM)	16	25	123	282	511	662	791	875	945	1014	1074	1120	1169	1200
Genotropin est. revenue (\$MM)	594	556	521	521	260	100	100	100	100	100	90	90	90	90
Royalties (asssume 14%) (\$MM)	2.3	3.5												
Total revenue (\$MM)	610	581	644	803	771	762	891	975	1045	1114	1164	1210	1259	1290
COGS			(71)	(88)	(85)	(84)	(98)	(107)	(115)	(123)	(128)	(133)	(138)	(142)
SG&A			(200)	(210)	(221)	(232)	(244)	(256)	(270)	(283)	(298)	(313)	(329)	(346)
Operational profits			373	505	465	446	549	611	661	708	738	764	792	802
Assume profit sharing @ 25%			95	128	118	113	139	155	168	180	188	194	201	204
Revenue to OPK	2	3	95	128	118	113	139	155	168	180	188	194	201	204

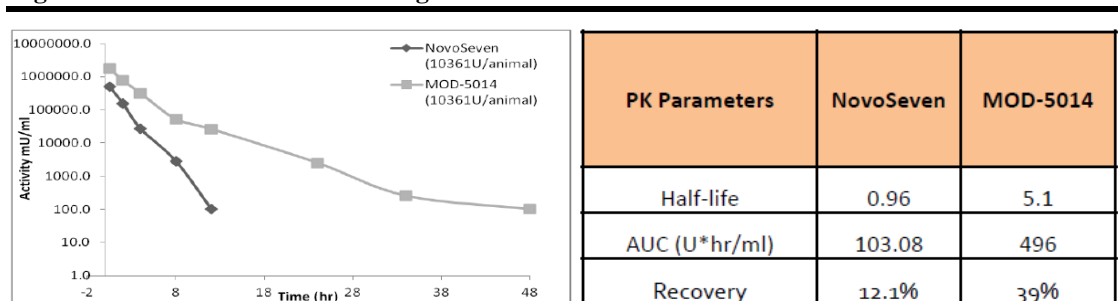
Source: Laidlaw & Company estimates

Factor VIIa-CTP (MOD-5014) is a novel, long-acting recombinant factor VIIa coupled with CTP technology to extend circulatory half-life without the use of polymers, encapsulation techniques, or nanoparticles.

Other earlier stage products in development. The leading developments include factor VIIa-CTP (MOD-5014) as a potential prophylactic and on-demand therapy in hemophilia, with Phase II study underway; and oxyntomolulin as a potential obesity treatment based on its appetite control potential.

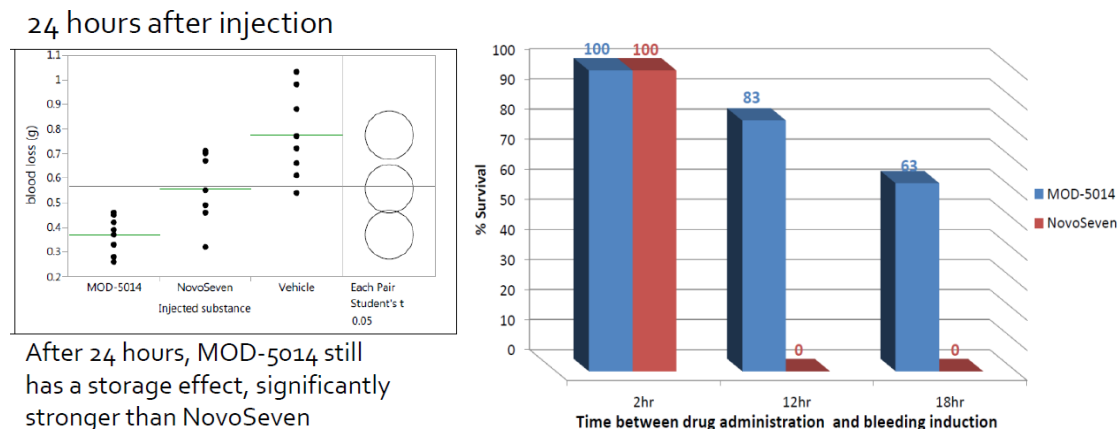
Factor VIIa-CTP (MOD-5014). It is a novel, long-acting recombinant factor VIIa coupled with CTP technology to extend circulatory half-life without the use of polymers, encapsulation techniques, or nanoparticles. Pre-clinical studies of MOD-5014 in hemophilic animal models demonstrated the drug could potentially be delivered via intravenous or subcutaneous means. MOD-5014 exhibited longer half-life (Figure 37) and longer time for preventing bleeding (Figure 38) than NovoSeven. The studies also demonstrated the drug can be injected less frequently during on-demand therapy, and two to three times weekly as prophylactic therapy. In addition, MOD-5014 in hemophilia A or B with inhibitors has been granted orphan status in the U.S. and Europe.

Figure 37: MOD-5014 exhibited longer half-life than NovoSeven



Source: Company presentation

Figure 38: MOD-5014 exhibited longer time for preventing bleeding than NovoSeven

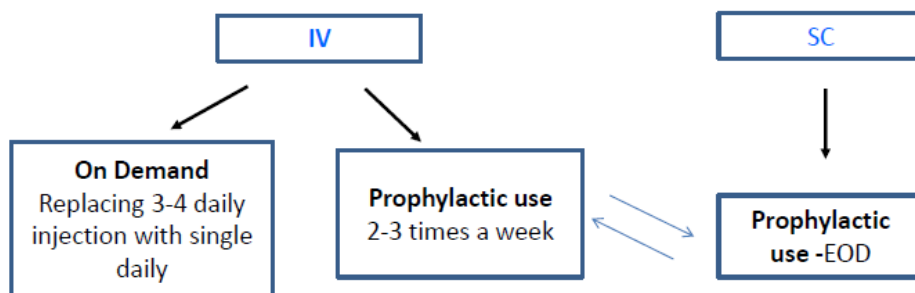


Source: Company presentation

Next steps. OPK recently commenced a Phase I/IIa study evaluating MOD-5014 in hemophilia A or B patients developing FVIII or FIX inhibitors during bleeding episode treatment. We estimate the top-line could be available in 4Q16. The study is an open-label, dose escalating trial that plans to enroll 24 patients to test six dose cohorts. The primary endpoint is to assess the acute safety and tolerability of single intravenous (IV) administration of escalating MOD-5014 doses in hemophilic subjects with and without inhibitors. The secondary endpoint is to evaluate the PK profile of single IV administration of escalating MOD-5014 doses.

In addition to the IV MOD-5014, OPK is also exploring a subcutaneously (s.c.) delivered MOD-5014. The rationale for the two different forms of MOD-5014 is that the IV drug could be used for on-demand and prophylactic use with higher dosing frequency. It is also suitable for patients with good vein access, such as young adults. The s.c. MOD-5014 could have utility as less frequent dosing prophylactic (Figure 39). The s.c. version could be used for patients with poor vein access, such as older adults and younger children. OPK is scheduled to start and complete the MOD-5014 (s.c.) Phase I study in 1H16.

Figure 39: IV and S.C. MOD-5014 could be used under different circumstances



Source: Company presentation

OPK is scheduled to conduct an End-of-Phase II (EOP2) meeting in 2H16 and plan to start a Phase II trial in s.c. MOD-5014 in 4Q16 with top-line expected in

OPK recently commenced a Phase I/IIa study evaluating MOD-5014 in hemophilia A or B patients developing FVIII or FIX inhibitors during bleeding episode treatment. We estimate the top-line could be available in 4Q16.

OPK is scheduled to start and complete the MOD-5014 (s.c.) Phase I study in 1H16.

4Q17. The company also plans to conduct an IV MOD-5014 Phase II/III trial in 1Q17 with top-line results possibly available in 2Q18.

Hemophilia Review. Hemophilia is a rare, hereditary (X-chromosome linked) disorder that could further divided into hemophilia A and B depending on deficiency of clotting factor (A with factor VIII and B with factor IX). Hemophilia A affects 1 in every 5,000-10,000 individual or approximately over 25,000 patients in the U.S. Hemophilia B affects 1 in every 25,000-30,000 individual or approximately over ~4,000 patients in the U.S. Replacement therapy is the main treatment modality for treating hemophilia with rFIX (such as BeneFIX from Pfizer) and rFVIII (such as Advate from Baxalta) as major products. Eloctate from Biogen is a new entrant.

In an estimated 20% of hemophilia patients (est. ~6,000), the development of high-titer inhibitors to FVIII after replacement therapy is the most serious complication of hemophilia therapy, resulting in a challenging condition for treating potential bleeding. Bypassing agents, such as factor eight inhibitor bypass activity (FEIBA) and recombinant factor VII (rFVIIa) are available therapies for the treatment of bleeds in patients developing inhibitor.

NovoSeven (rFVIIa) from Novo Nordisk is the overwhelming dominant product for the treatment of hemophilia patients who have developed antibodies or inhibitors and with reported 2014 sales of DKr 9.1 billion (est. \$1.3 billion). The total market for Factor VIIa is approximately \$1.7 billion. Due to Factor VIIa's short half-life, currently therapy, such as NovoSeven would require multiple infusions of intravenous (IV) formulation to treat a bleeding episode. NovoSeven generally is dosed 3 to 4 times a day for treating bleeding episodes; and one to two doses daily as a prophylactic treatment.

While Novoseven's patents regarding its sequence expired between 2009 and 2011 in major countries, the sales of the product continue to grow. The U.S. formulation and process patent is expected to expire in 2017 and 2019, respectively, according to Novo Nordisk's filings.

Competitive Landscape: other FVIIa in development programs include:

LR769 by rEVO Biologics and LFB SA currently is in Phase III (PerSept 1, 2 and 3) study in adult and adolescent patients with congenital hemophilia A or B with inhibitors to FVIII and FIX. The company in 1Q15 reported that the Data Monitoring Committee has issued a go-ahead for the initiation of PerSept 2 and 3 study to evaluate the safety and efficacy of LR769 in pediatric patients and around surgeries, respectively, with trial to start in 2H15. LR769 is produced from the milk of transgenic rabbits. It is not a long-acting rFVIIa, but potentially a bio-similar with lower production costs.

CSL689 rVIIa-FP from CSL Behring is an albumin-linked recombinant factor VIIa with extended half-life. The company has completed a Phase I study in healthy volunteers in 2013; with a Phase

II/III trial to treat patients with inhibitors to commence in 2015. Clinicaltrial.gov information suggests that the estimated study completion date is May 2018. One potential concern for albumin-linked recombinant product is the possible weaker potency.

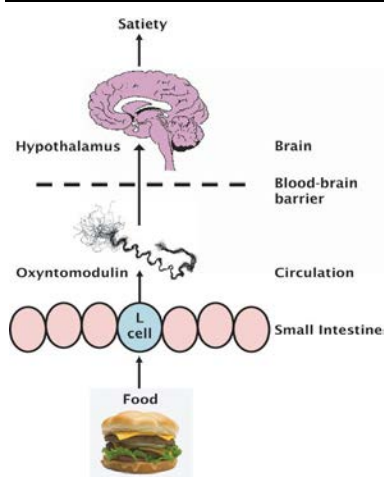
PF-05280602/CB 813d from Catalyst Biosciences reported Phase I 25-patient PK study results in 2Q15 that the drug demonstrated pharmacological efficacy as measured by significant shortening of aPTT (activated partial thromboplastin time) and PT (prothrombin time) for up to 48 hours post dosing. CB 813d is an improved next-generation and long-acting (1x/weekly) coagulation Factor VIIa variant.

BAX 817 from Baxalta is currently undergoing Phase III study and the company reported positive results in 1Q15 as the study met primary endpoint of successful resolution of acute bleeding episodes at 12 hours with both on-demand treatment regimens, with an overall success rate of 92%. The company plans to file BLA later in 2015. BAX 817 is a short-acting rFVIIa and possibly would be positioned as a biosimilar.

Oxyntomodulin. OPK is developing MOD-6031, a long acting (via reversible pegylation technology) glucagon-like peptide-1 (GLP-1)/glucagon dual receptor agonist as a potential treatment for obesity. MOD-6031 is an improved version of oxyntomodulin (OXM) – a natural appetite suppressor (Figure 40). Oxyntomodulin is a peptide secreted from the L cells of the gut after the consumption of food. OXM is potentially more potent than GLP1 agonist for treating obesity. OXM needs to cross the blood-brain barrier to induce satiety.

OPK is developing MOD-6031, a long acting (via reversible pegylation technology) glucagon-like peptide-1 (GLP-1)/glucagon dual receptor agonist as a potential treatment for obesity.

Figure 40: Oxyntomodulin is a nature's appetite control mechanism



Source: Company presentation

After several academic pre-clinical animal-model and clinical studies evaluating OXM in weight reduction, OPK conducted a pre-clinical analysis in mice model to evaluate MOD-6031's potential in weight loss and reduction of food intake. The study demonstrated that MOD-6031 is superior to that of native OXM and

The pre-clinical study demonstrated that MOD-6031 is superior to that of native OXM and PEG-OXM based on weight loss, required reduced dose and ability for delivering the drug into brain

PEG-OXM (Figure 41) based on weight loss, required reduced dose and ability for delivering the drug into brain.

Figure 41: MOD-6031 demonstrated superior to OXM in weight reduction

Treatment	Injection Frequency	Dose per Injection	Cumulative Dose in 30 Days	Cumulative Weight Loss Day 30 (%)	Cumulative Food Intake Reduction (%)
Formulation Buffer	2x per Day	--	--	0.3% Gain	--
Native OXM	2x per Day	6,000 nm	348,000 nm	16.6% Loss	12% Less
PEG-OXM	1X per Week	6000nm	30,000nm	1.6% Loss	1% Less
MOD-6030	1x per Week	6,000 nm	30,000 nm	27.6% Loss	30% Less

Source: Company presentation

In addition, the study also illustrated that MOD-6031 could induce glucose tolerance and improved glycemic and lipid profile in DIO mice model. Together, MOD-6031 has the potential as a better long-term obesity and type II diabetes therapy.

OPK is currently conducting additional pre-clinical studies, such as toxicology studies with the expectation to commence a Phase I trial possibly in early 1Q16.

Long-acting biologics delivery platforms: From the Prolor Biotech acquisition, OPK gained two platform technologies that could extend the half-life of therapeutic products for different types of molecules: CTP technology (for recombinant proteins) and reversible pegylation technology (for peptides and small molecules).

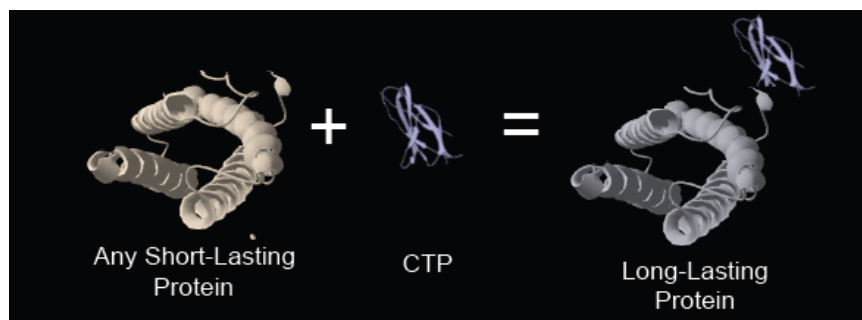
The CPT technology is to attach a short, naturally-occurring peptide – carboxy terminal peptide (CTP) of the beta chain of human chorionic gonadotropin – to a protein to extend its circulatory half-life

CTP (Carboxyl terminal peptide) technology. The technology is to attach a short, naturally-occurring peptide – carboxy terminal peptide (CTP) of the beta chain of human chorionic gonadotropin – to a protein to extend its circulatory half-life (Figure 42). CTP is a peptide containing four serine or O-linked oligosaccharides (Figure 43). It has been postulated that the O-linked oligosaccharides add flexibility, hydrophilicity, and stability to the protein, and therefore, the protein coupled with CTP retains the proper conformation and enable the complex to bind to its corresponding receptor and retains bioactivity. Further, the O-linked oligosaccharides play an important role in preventing plasma clearance and thus increasing the half-life of the therapeutic protein to which CTP is attached during the circulation¹. In addition, given the end of O-linked oligosaccharides are of negatively charged sialic acid; additional protein half-life can be achieved since it is much slower for a negative charged entity to be cleared via glomerular filtration in the kidney. It is noted that the half-life of

¹ Fares, F., et. al., Int. J. Cell Biol. (2011) 2011:

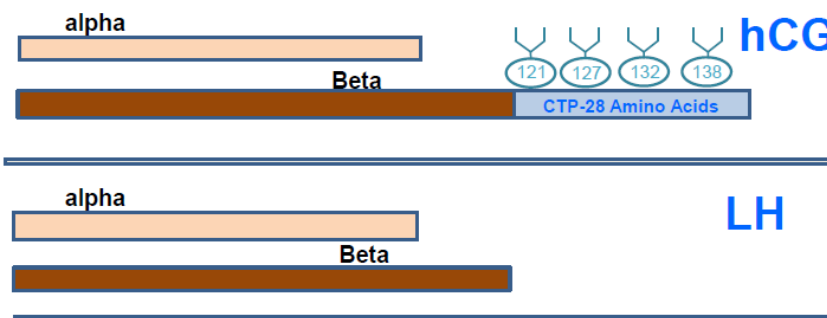
human chorionic gonadotropin is five times longer than that of human luteinizing hormone (hLH); while the amino acid sequence of both hormones is essentially identical (Figure 43).

Figure 42: CTP technology increases protein circulation time



Source: Company presentation

Figure 43: CTP technology increases protein circulation time



Source: Company presentation

Making long-acting protein via the CPT technology is well validated approach for biologics therapeutics. Two examples of marketed biologics are Elonva (a long-acting FSH-CTP approved in Europe) of Merck and human chorionic gonadotropin (hCG), of which CTP is natural part of it (sold by Merck-Serono, Merck & Co. and Ferring).

Reversible pegylation technology. It is a technology initially to link a drug to polyethylene glycol (PEG) via a hydrolysable linker. Upon entering the body and into the proper tissue, the linker of the molecule is hydrolyzed and the drug is released for treatment (Figure 44).

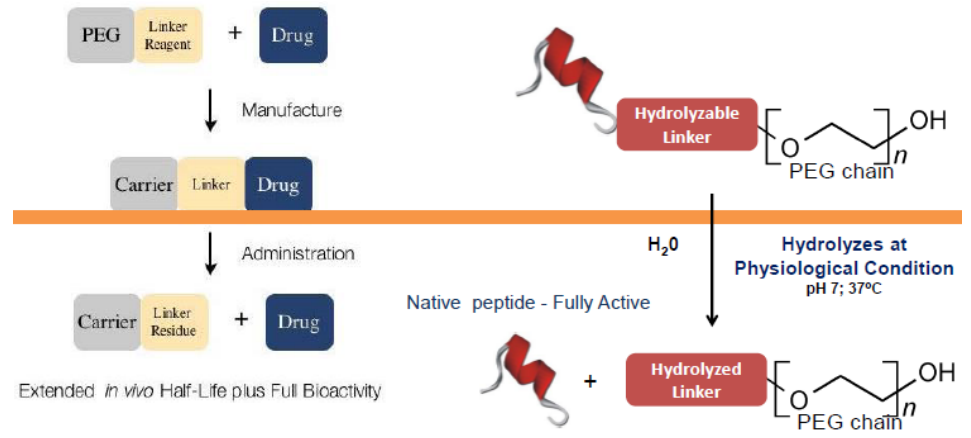
There are several advantages of reversible pegylation technology, which include:

- It could deliver long lasting fully active authentic peptide;
- It could provide slow, supporting predictable pharmacokinetic pattern given it is a 1st order hydrolysis reaction;
- It allows development of long acting peptides and small molecules that need to cross the Blood Brain Barrier (BBB);
- It affords dose reduction; and

Reversible pegylation technology is a technology initially to link a drug to polyethylene glycol (PEG) via a hydrolysable linker. Upon entering the body and into the proper tissue, the linker of the molecule is hydrolyzed and the drug is released for treatment

- Toxicological studies demonstrated that PEG30-Linker (REV-PEG) is well tolerated and can be considered safe following repeated administrations.

Figure 44: Reversible pegylation technology



Source: Company presentation

Acquisition of EirGen Pharma. OPK announced in 2Q15 the acquisition of Waterford, Ireland-based EirGen Pharma for \$135MM. EirGen Pharma is profitable and has filed multiple product applications with the U.S. (FDA) and other countries. EirGen has a strong development pipeline with over 20 niche and high barrier to entry drugs. EirGen also owns sophisticated pharmaceutical manufacturing facilities in Ireland. We anticipate the EirGen acquisition could afford OPK expanded manufacture capability for producing the company’s current and future products, such as Rayaldee. Additional benefits of the EirGen acquisition could include synergies to OPK’s active pharmaceutical ingredient (API) production operation (such as its subsidiary FineTech); and potential low tax advantages.

Strategic Investments and International Business Could Add Additional Upside Longer Term

In addition to develop and commercialize healthcare products, OPK also participate in strategic investment in early stage companies that perceive to have valuable proprietary technology and significant potential to create value for OPKO as a shareholder. The invested companies include:

- ARNO Therapeutics (~4% equity interest). The company affords anti-progestin therapy for breast (Phase II) , endometrial and prostate cancers
- Zebra Biologics, Inc. (~27% equity interest). The company affords combinatorial antibody libraries based on function in human cell screens
- OAO Pharmsynthez (~17% equity interest). The company is a Russian developer and marketer of new drugs
- RXi Pharmaceuticals (~10% equity interest). The company affords sRNA to prevent hypertrophic scars (Phase II)
- Cocrystal Pharma, Inc. (~8% equity interest). The company affords new anti-virals (HCV and flu) superior molecules for combination therapy (pan-genotypic)
- Sevion Therapeutics (~4% equity interest). The company affords antibodies against difficult targets (e.g., G protein-coupled receptor and ion channels)
- Neovasc (~5% equity interest). The company affords cardiology devices (transcutaneous mitral valve)
- ChromaDex (~2% equity interest). The company affords new nutritional supplement APIs
- MabVax Therapeutics (~7% equity interest). The company affords cancer immunotherapy.
- SciVac Ltd (~45% equity interest). The company affords third-generation hepatitis B vaccine. It also in-licensed an early-stage enzyme-based product designated S-Graft, a recombinant human deoxyribonuclease I, a repurposed biological therapeutic intended for the prevention and treatment of graft-versus-host disease (GVHD).

Further, OPK has acquired or developed subsidiaries internationally. Key operations include:

- **OPKO Chile.** It imports, commercializes, and distributes over 100 medical products to private, hospital, and institutional markets in Chile.

The focuses of the operation are anti-infective and anti-inflammatories with emphasis in ophthalmology, gynecology, diabetes, and arterial hypertension. Further, OPKO Chile also markets and distributes products for the cardiovascular, digestive, respiratory, and central nervous systems.

- **OPKO EU.** It is based on Barcelona, Spain. It engages in the development, manufacturing, marketing, and sale of a pharmaceutical, nutraceutical, and veterinary products in Europe.
- **OPKO Mexico.** It engages in the manufacture, marketing, and distribution of over 25 products, primarily in the generics market in Mexico. Its product line includes a wide variety of eye drops, including lubricants, antibiotics, and non-steroidal anti-inflammatory drugs.
- **OPKO FineTech.** It is a profitable Israeli company engaged in the development and production of high-value, high-potency specialty APIs. Examples of their APIs include cabergoline, latanoprost, nabilone and donepezil hydrochloride. In addition to production capabilities, other expertise of the company includes analytical chemistry and organic synthesis.
- **EirGen Pharma.** Acquired recently by OPK, it is Waterford, Ireland-based leading pharmaceutical contract manufacturing and supply of high-potency pharmaceutical products produced from high containment facilities to global markets.

Financial Projections and Valuation

The company recently reported the 2Q15 financial results with \$220 MM cash. Given the deal for Bio-Reference Laboratories (BRL) acquisition could close in late August, we are modeling one-third of projected financial operation from BRL into consolidated OPK financial model for 3Q15.

Our discounted cash flow analysis suggested a one-year target value for OPK of **\$22.00** based on cash flow until 2024 with a discount rate of 12%, a terminal growth rate of 7%, and total shares outstanding of 551 million shares as of 2H16.

DCF analysis

Cash driven NPV	2016	2017	2018	2019	2020	2021	2022	2023	2024
Cash Flow Before Interest and Taxes	92.1	212.2	339.0	557.4	735.3	893.2	1,046.8	1,222.9	1,413.3
Tax Rate	37%	37%	37%	37%	37%	37%	37%	37%	37%
Adjusted EBIT (1-Tax Rate)	58.0	133.7	213.6	351.2	463.2	562.7	659.5	770.4	890.4
Growth		130%	60%	64%	32%	21%	17%	17%	16%
Depreciation	42.0	44.1	46.3	48.6	51.1	53.6	56.3	59.1	62.1
Capital Expenditures	(25.7)	(27.0)	(28.4)	(29.8)	(31.3)	(32.8)	(34.5)	(36.2)	(38.0)
Investment in Non-Cash Working Capital	53.6	56.2	59.0	62.0	65.1	68.3	71.8	75.4	79.1
FCFF	128	207	291	432	548	652	753	869	994
Growth		62%	40%	49%	27%	19%	16%	15%	14%
PV of Net FCFF	122	178	224	299	340	363	376	389	400

Source: Laidlaw & Company estimates

Comparable analysis

Discounted Cash Flow (DCF) and Equity Valuation (\$ MM):	
Assumed Discount Rate (%)	12%
Discounted Net Cash Flow (2016-'24)	\$2,667
Terminal Growth Rate (%)	7%
Implied Terminal Year FCF Multiple	23.5x
Present Value of Terminal Value	\$9,267
Terminal Value as % of total	77.7%
Enterprise Value	\$11,934
Add: Net Cash	200
Equity Value	\$12,134
Shares Outstanding 2016E (000)	551
Equity Value per Share	\$22.01

Source: Company reports and Laidlaw & Company estimates

Major Risks

Risks of clinical study failure. One of the key risks for healthcare product developer is failure of clinical studies that could potentially result in sunk costs in both capital and time lost. OPK currently has several mid- to late stage clinical trials underway. Failures of these studies, especially the Phase III pivotal trials, could have significant negative impact on share value. More specifically, clinical study success of MOD-4023 (hGH-CTP) is very important given it accounts for substantial valuation of OPK share value.

Regulatory success is important. Given the company currently has several products (in-house development and partnered) under regulatory agency review, whether to receive positive response and approval could have significant impact on share value. Although clinical study results for the several drugs currently under FDA review are rather robust; it remains possible that the agency may not grant approval or request additional clinical information or studies before considering approval. A scenario of this nature could have significant and immediate negative impact on OPK shareholder value.

Merger and acquisition risks. Although acquisition is a faster way to accomplish financial and strategic goals, it bears a number of risks especially post-merger. For example, due to the differences of corporate culture and mentality of operation, there are no assurance a successful integration can be accomplished immediately.

Successful reimbursement is critical for commercial success. Given the high price of medical products, it is important for most patients who will use them only if the diagnostic test or pharmaceutical products are reimbursed by third party payers, such as Medicare or private insurers. There is no certainty that the company's current or future products can be reimbursed by private or public parties. If so, we believe the revenue growth for such drug or diagnostic test could be limited.

Products may not be approved or reach anticipated sales. Although OPK's current pipeline products have exhibited the potential to generate positive clinical outcomes from current and future trials; it remains too early to project whether any of these products would be approved by regulatory agencies. Even if the products were to enter the market, sales could be significantly below projections due to the specific product label under approval, physician consensus for prescribing the drug, changes of treatment paradigms, entrance of competitors, and possibly the changes in pricing flexibility and payer reimbursement. A revenue outlook below expectations could also negatively affect OPK shareholder value.

Ex-U.S. market risks. Given several OPK operations are out-side of the U.S. and some are in emerging markets, certain risks, such as macroeconomic

volatility, geopolitical risk and currency fluctuations could all impact on the revenue generated from and operation in these territories.

Concentrated insider ownership. Given senior management and other insiders own near 50% of OPK shares, the insider ownership is very concentrated. As such, insiders could have significant control and therefore, with the potential risk of creating price volatility. Highly concentrated insider ownership could also have impact on delaying or preventing a change in control of the company.

Management

Phillip Frost, M.D. is OPKO Health CEO and Chairman since 2007 after the merger of Acuity Pharmaceuticals, Froptix Corporation and eXegenics. Dr. Frost was the Chairman of the Board of Teva from March 2010 to February 2015. Prior, he was Vice Chairman of Teva since 2006 when Teva acquired IVAX Corporation. Prior to Teva, he served as Chairman of the Board and CEO of IVAX since 1987. Prior to IVAX from 1972 to 1986, he was Chairman of the Department of Dermatology at Mt. Sinai Medical Center of Greater Miami, Miami Beach. From 1972 to 1986, Dr. Frost served as Chairman of the Board of Key Pharmaceuticals until it was acquired by Schering Plough. Dr. Frost served as Chairman of the Board of Ladenburg Thalmann Financial Services in July 2006 and has been served as director from 2001 until 2002 and again since 2004. Dr. Frost has served as Chairman of the Board of Directors of Prolor Biotech. Dr. Frost holds a M.D. degree from the Albert Einstein College of Medicine.

Jane H. Hsiao, Ph.D. has served as Vice-Chairman and Chief Technical Officer of OPKO Health since May 2007. Prior to joining OPKO Health from 1995 to 2006, Dr. Dr. Hsiao served as the Vice Chairman-Technical Affairs of IVAX, and prior from 1998 to 2006, she served as Chairman, CEO and President of IVAX Animal Health. Dr. Hsiao has served as Chairman of the Board of each of Safestitch Medical, and Non-Invasive Monitoring Systems, since September 2007 and October 2008, respectively, and was named Interim CEO of Non-Invasive Monitoring Systems in February 2012. Dr. Hsiao holds a Ph.D. degree in Pharmaceutical Chemistry and Medicinal Chemistry from the University of Illinois, Chicago.

Steven D. Rubin has served as Executive Vice President—Administration and as a director since 2007. Prior, from 2001 to 2006, Mr. Rubin served as the Senior Vice President, General Counsel and Secretary of IVAX. Mr. Rubin currently serves on the Board of Directors of multiple companies of different industry sectors, which include Safestitch Medical, Tiger Media, Kidville, Non-Invasive Monitoring Systems, Tiger X Medical, Castle Brands, and Neovasc.

Adam Logal has served as CFO and Chief Accounting Officer and Treasurer of OPKO Health since 2014, and served as Accounting Officer and Treasurer since 2007. Prior joining OPKO From 2002 to 2007, Mr. Logal served in senior management of Nabi Biopharmaceuticals with most recent as Senior Director of Accounting and Reporting.

Income Statement

OPKO Health – Income Statement

(\$'MM)	2012	2013	2014	1Q15	2Q15	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue													
Products (Pharmaceuticals)	45.3	68.2	77.0	15.5	22.8	20.3	23.6	82.2	140.8	255.1	371.4	586.2	756.4
Revenue from services (Diagnostics)	1.7	11.7	8.7	2.1	1.9	85.6	270.7	360.3	1,119.0	1,300.8	1,499.8	1,712.7	1,956.8
Revenue from transfer of intellectual property	0.0	16.7	5.5	12.5	17.7	17.5	17.5	65.3	66.6	66.6	67.2	67.9	68.6
Total revenue	47.0	96.5	91.1	30.1	42.4	123.4	311.8	507.7	1,325.7	1,622.5	1,938.4	2,366.9	2,781.8
Costs of revenues	27.9	48.9	48.0	10.3	14.4	57.7	161.0	243.5	624.7	720.3	826.4	944.5	1,077.8
Gross Incomes	19.2	47.7	43.1	19.8	28.0	65.7	150.7	264.2	701.0	902.1	1,112.0	1,422.3	1,704.0
Selling, general and administrative	27.8	55.3	57.9	17.4	20.9	48.3	106.1	192.8	471.8	544.2	620.5	706.9	804.9
Research and development	19.5	53.9	83.6	25.5	29.6	30.5	30.8	116.3	125.6	134.4	141.1	146.8	152.6
In process research and development	0.0	0.0	12.1	-	0.0	0.0	-	0.0	0.0	0.0	0.0	0.0	0.0
Contingent consideration	0.8	6.9	24.4	5.2	(0.3)	4.0	4.0	12.8	12.8	12.8	12.8	12.8	12.8
Amortization of intangible assets	8.3	11.1	10.9	2.7	3.2	6.5	6.5	18.8	18.8	18.8	18.8	18.8	18.8
Grant repayment	0.0	0.0	0.0	25.9	0.0	0.0	-	25.9	0.0	0.0	0.0	0.0	0.0
Total Operating Expenses	56.4	127.3	188.9	76.7	53.4	89.2	147.3	366.6	629.0	710.2	793.3	885.3	989.2
Total costs and expenses	84.3	176.2	236.9	87.0	67.8	147.0	308.4	610.2	1,253.8	1,430.5	1,619.8	1,829.8	2,067.0
Operating Incomes (losses)	(37.3)	(79.6)	(145.8)	(56.9)	(25.4)	(23.5)	3.4	(102.4)	72.0	191.9	318.7	537.0	714.8
Interest income	0.2	0.4	0.8	0.0	0.1	0.1	0.1	0.2	0.8	0.9	1.0	1.1	1.1
Interest expense	(1.4)	(13.8)	(12.3)	(2.6)	(1.0)	(1.0)	(1.0)	(5.5)	(5.5)	(5.5)	(5.5)	(5.5)	(5.5)
Fair value changes of derivative instruments, net	1.2	(45.9)	(10.6)	(49.8)	(16.6)	(15.0)	18.0	(63.3)	(18.0)	(18.0)	(18.0)	(18.0)	(18.0)
Other income (expense), net	0.2	34.8	(3.1)	(1.5)	0.8	3.0	(1.7)	0.6	0.6	0.6	0.6	0.6	0.6
Total Other Income, net	0.2	(24.6)	(25.2)	(53.9)	(16.7)	(12.9)	15.4	(68.2)	(22.2)	(22.1)	(22.0)	(21.9)	(21.9)
Income before tax	(37.1)	(104.2)	(171.0)	(110.8)	(42.1)	(36.5)	18.8	(170.6)	49.8	169.8	296.7	515.1	692.9
Tax Rate									37%	37%	37%	37%	37%
Tax	9.6	(1.7)	(0.0)	(5.5)	(0.3)	(1.0)	(1.0)	(7.8)	(18.4)	(62.8)	(109.8)	(190.6)	(256.4)
Loss before investment losses	(27.5)	(105.9)	(171.1)	(116.3)	(42.4)	(37.5)	17.8	(178.3)	31.4	107.0	186.9	324.5	436.5
Loss from investments in investees	(2.1)	(11.5)	(3.6)	(1.8)	(0.8)	(1.2)	(1.4)	(5.2)	(3.0)	(3.0)	(3.0)	(3.0)	(3.0)
Net income (loss)	(29.5)	(117.3)	(174.6)	(118.0)	(43.2)	(38.7)	16.4	(183.5)	28.4	104.0	183.9	321.5	433.5
Net loss attributable to noncontrolling interests	(0.5)	(2.9)	(3.0)	(0.9)	(0.5)	(0.8)	(0.9)	(3.1)	(3.1)	(3.0)	(3.0)	(3.0)	(3.0)
Net Income (Loss) Applicable to Common Shareholders	(31.3)	(114.8)	(171.7)	(117.1)	(42.7)	(37.9)	17.3	(180.4)	31.5	107.0	186.9	324.5	436.5
Net Earnings (Losses) Per Share—Basic and Diluted	(\$0.11)	(\$0.32)	(\$0.41)	(\$0.26)	(\$0.09)	(\$0.08)	\$0.03	(\$0.37)	\$0.06	\$0.22	\$0.33	\$0.65	\$0.77
Shares outstanding—basic and diluted	295.8	355.1	422.0	446.5	456.5	482.1	543.3	482.1	551.3	490.1	559.3	498.1	567.3
	295.8	355.1	422.0	446.5	456.5	482.1	543.3	482.1	551.3	490.1	559.3	498.1	567.3
Margin Analysis (% of Sales/Revenue)													
Costs of goods	59%	61%	56%	59%	58%	58%	55%	55%	50%	46%	44%	41%	40%
Gross margin	41%	39%	44%	41%	42%	42%	45%	45%	50%	54%	56%	59%	60%
R&D	41%	56%	92%	85%	70%	25%	10%	23%	9%	8%	7%	6%	5%
MG&A	59%	57%	64%	58%	49%	39%	34%	38%	36%	34%	32%	30%	29%
Operating Income (loss)	-79%	-82%	-160%	-189%	-60%	-19%	1%	-20%	5%	12%	16%	23%	26%
Pretax	-79%	-108%	-188%	-368%	-99%	-30%	6%	-34%	4%	10%	15%	22%	25%
Tax Rate													
Net Income	-67%	-119%	-188%	-389%	-101%	-31%	6%	-36%	2%	7%	10%	14%	16%
Financial Indicator Growth Analysis (YoY%)													
Products (Pharmaceuticals)	63%	50%	13%	-22%	7%	17%	27%	7%	71%	81%	46%	58%	29%
Revenue from services (Diagnostics)	1196%	567%	-26%	5%	-11%	3349%	13035%	4057%	211%	16%	15%	14%	14%
Revenue from transfer of intellectual property	N.A.	N.A.	-67%	2532%	N.A.	N.A.	251%	1092%	1%	1%	1%	1%	1%
Total Revenue	68%	105%	-6%	35%	80%	524%	1121%	457%	161%	22%	19%	22%	18%
Gross Profit	79%	149%	-10%	100%	155%	659%	1008%	513%	165%	29%	23%	28%	20%
Cost of Sales	62%	75%	-2%	-17%	15%	419%	1250%	407%	157%	15%	15%	14%	14%
R&D	72%	176%	55%	21%	82%	48%	19%	39%	8%	7%	5%	4%	4%
SG&A	45%	99%	5%	26%	41%	245%	596%	233%	3%	9%	9%	9%	8%
Contingent consideration	NA	785%	252%	98%	-118%	-80%	987%	-47%	0%	10%	5%	6%	5%
Operating income (loss)	61%	114%	83%	88%	-27%	-51%	-111%	-30%	-170%	167%	66%	69%	33%
Total Other Income, net	-116%	-15001%	3%	343%	-280%	775%	-174%	170%	-67%	0%	0%	0%	0%
Pretax Income	53%	181%	64%	161%	65%	-27%	-135%	0%	-129%	241%	75%	74%	35%
Net Income	754%	267%	49%	163%	68%	-22%	-133%	5%	-117%	240%	75%	74%	35%
EPS	711%	206%	26%	143%	52%	-31%	-126%	-8%	-115%	282%	53%	95%	18%

Yale Jen, Ph.D. 212-953-4978

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

Balance Sheet

OPK Health – Balance Sheet

(\$'MM)	2012	2013	2014	1Q15	2Q15	3Q15E	4Q15E	2015E	2016E
Assets									
Cash and cash equivalents	27.4	185.8	96.9	348.2	221.2	136.7	140.7	140.7	251.2
Short term investments	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Liquid assets	27.4	185.8	96.9	348.2	221.2	136.7	140.7	140.7	251.2
Accounts receivable	21.2	19.8	20.0	19.1	27.0	325.4	325.3	325.3	354.5
Inventories	22.3	18.1	16.6	18.3	20.5	42.2	45.0	45.0	57.1
Prepaid Expenses and Other current assets	7.9	19.1	9.4	8.4	9.6	59.2	60.6	60.6	65.0
Marketable Securities	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Current Assets of Discontinued Operations	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Current Assets	78.7	242.7	142.9	394.0	278.3	563.5	571.5	571.5	727.9
Property and equipment, net	16.5	17.0	16.4	15.1	23.4	96.4	97.4	97.4	99.7
Intangible Assets	95.8	74.5	62.6	59.4	94.2	365.8	370.8	370.8	371.8
In-process research and development	0.0	793.3	793.2	793.0	812.4	810.4	808.4	808.4	805.4
Goodwill	80.5	226.4	224.3	223.2	289.6	1,085.2	1,092.2	1,092.2	1,096.2
Investments, net	15.6	30.7	22.5	22.4	21.4	26.6	25.6	25.6	24.6
Other Assets	2.8	6.9	5.8	5.1	6.0	108.3	108.3	108.3	110.3
Total Assets	289.8	1,391.5	1,267.7	1,512.2	1,525.5	3,056.3	3,074.4	3,074.4	3,125.7
Liabilities and Stockholders' Equity									
Accounts payable	10.2	13.4	8.7	10.5	16.0	82.2	84.0	84.0	88.1
Accrued Expenses	24.7	65.9	60.9	158.8	149.8	190.7	194.8	194.8	205.1
Current portion of lines of credit and notes payable	17.5	12.6	13.5	13.6	14.6	69.2	68.7	68.7	69.7
Current Liabilities of discontinued operations	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Current Liabilities	52.4	91.9	83.1	182.8	180.5	342.1	347.5	347.5	362.9
Three percent convertible senior notes	0.0	211.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0
2033 Senior Notes	0.0	0.0	131.5	106.7	109.2	110.0	108.0	108.0	100.0
25/8 percent convertible subordinated notes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other long-term liabilities, principally deferred revenue and deferred tax liabilities	34.2	214.8	217.4	410.2	408.8	419.9	417.5	417.5	426.9
Total Liabilities	86.6	518.5	431.9	699.7	698.5	872.0	873.0	873.0	889.8
Common stock	3.1	4.1	4.3	4.6	4.6	5.4	5.4	5.4	5.4
Series D Preferred Stock	24.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Treasury Stock	(7.5)	(7.4)	(4.1)	(4.1)	(3.6)	(3.4)	(3.3)	(3.3)	(3.5)
Additional paid-in capital	565.2	1,379.4	1,529.1	1,628.8	1,687.4	2,922.2	2,922.4	2,922.4	2,932.7
Accumulated other comprehensive income	7.4	3.4	(12.4)	(17.5)	(18.9)	(20.0)	(20.5)	(20.5)	(27.6)
Accumulated Deficit	(388.8)	(503.2)	(674.8)	(792.0)	(834.7)	(712.4)	(695.1)	(695.1)	(663.6)
Total Stockholders' Equity	203.8	876.4	842.1	819.9	834.8	2,191.8	2,208.9	2,208.9	2,243.4
Non-controlling Interest	(0.5)	(3.4)	(6.4)	(7.3)	(7.8)	(7.5)	(7.5)	(7.5)	(7.5)
Total Liabilities and Stockholders' Equity	289.8	1,391.5	1,267.7	1,512.2	1,525.5	3,056.3	3,074.4	3,074.4	3,125.7

Yale Jen, Ph.D. 212-953-4978

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

Cash flow Statement

OPKO Health – Cash Flow Statement									
(\$'MM)	2012	2013	2014	1Q15	2Q15	3Q15E	4Q15E	2015E	2016E
Cash Flows From Operating Activities:									
Net loss **	(29.5)	(117.3)	(174.6)	(118.0)	(43.2)	(38.4)	16.8	(182.9)	30.5
Income from discontinued operations, net of tax	(0.1)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<i>Adjustments to reconcile net loss to net cash used in operating activities:</i>									
Depreciation and amortization	10.2	15.2	14.9	3.5	4.2	10.7	10.5	28.9	42.0
Non-cash interest on convertible senior notes	0.0	6.0	5.7	1.1	0.6	1.2	1.1	4.0	4.0
Amortization of deferred financing costs	0.0	1.2	2.0	0.8	0.1	0.2	0.2	1.3	1.5
Losses from investments in investees	2.1	11.5	3.6	1.8	0.8	0.4	0.7	3.7	3.0
Equity-based compensation – employees and non-employees	5.1	11.0	14.8	7.4	6.7	5.7	6.0	25.8	24.0
Provision for (recovery of) bad debts	(0.1)	1.0	0.6	0.2	0.5	0.1	0.2	0.9	1.0
Provision for inventory obsolescence	2.7	2.0	1.1	0.2	0.5	0.3	0.2	1.2	0.7
Provision for inventory reserves	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Revenue from receipt of equity	(0.2)	(12.7)	(0.2)	(0.1)	(0.1)	(0.1)	(0.1)	(0.3)	(1.5)
Unrealized gain on investments, available for sale	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Realized Gain on sale of equity securities	0.0	(29.9)	0.2	(0.2)	0.0	0.0	(0.1)	(0.3)	(0.4)
Loss on conversion of 3.00% convertible senior notes	0.0	8.7	(2.7)	0.3	(0.0)	(0.2)	(0.1)	(0.0)	(0.6)
Loss on sale of property, plant and equipment	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Change in fair value of derivatives instruments	(1.3)	36.5	10.6	49.8	16.6	15.0	(18.0)	63.3	18.0
Change in fair value of contingent consideration	0.8	6.9	24.4	5.2	(0.3)	4.0	4.0	12.8	12.8
Deferred income tax (benefit)/provision	(10.0)	0.6	1.0	0.0	0.0	0.0	0.0	0.0	0.0
In-process research and development	0.0	0.0	12.1	0.0	0.0	0.0	0.0	0.0	0.0
<i>Changes in operating assets and liabilities:</i>									
Accounts receivable	0.8	0.8	(3.9)	(0.1)	(4.7)	(298.4)	0.1	(303.1)	(29.2)
Inventory	(5.8)	1.9	(1.8)	(2.6)	(0.6)	(21.7)	(2.8)	(27.8)	(12.1)
Prepaid Expenses and other current assets	(2.9)	(1.1)	3.2	0.9	0.2	(49.6)	(1.4)	(49.8)	(4.4)
Other Assets	(0.4)	(0.5)	(3.4)	(0.5)	(0.0)	0.0	0.0	(0.5)	0.0
Accounts Payable	1.2	1.8	(3.9)	2.1	5.0	66.1	1.8	75.0	4.1
Foreign currency measurement	0.1	(2.4)	0.9	0.5	(0.2)	(0.5)	(0.3)	(0.5)	(0.3)
Accrued Expenses and other liabilities	1.9	0.8	4.9	4.4	(1.7)	40.9	4.1	47.7	10.3
Cash provided by operating activities of discontinued operations	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Deferred Revenue	0.0	0.0	0.0	282.2	(18.3)	181.8	(16.8)	428.9	20.0
Net Cash from Operating Activities	(25.4)	(58.2)	(90.4)	238.8	(34.1)	(82.4)	6.1	128.4	123.3
Cash Flows From Investing Activities:									
Investments in investees	(3.4)	(17.4)	(0.6)	0.0	(2.3)	(0.2)	(0.3)	(2.8)	(17.0)
Proceeds from sale of equity securities	0.0	30.6	1.3	0.0	0.0	0.0	0.0	0.0	0.0
Acquisition of businesses, net of cash acquired	(19.1)	20.5	(1.7)	0.0	(94.7)	0.0	0.0	(94.7)	0.0
Purchase of marketable securities	(25.8)	(50.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Maturities of short-term marketable securities	0.0	50.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from the sale of property, plant, and equipment	25.0	0.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Capital expenditures	(1.5)	(4.0)	(4.7)	(0.4)	(1.1)	(1.2)	(1.5)	(4.1)	(5.0)
Cash provided by investing activities from discontinued operations	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Cash from Investing Activities	(24.8)	30.3	(5.7)	(0.4)	(98.1)	(1.4)	(1.8)	(101.7)	(22.0)
Cash Flows From Financing Activities:									
Issuance of 3.00% convertible senior notes, net	0.0	170.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Issuance of common stock, net	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Issuance of common stock held in the treasury	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Redemption of Series A Preferred Stock	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Payment of Series D dividends	0.0	(3.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from the exercise of common stock options and warrants	2.3	23.4	12.9	12.7	4.7	2.0	3.0	22.4	23.0
Borrowing of lines of credit	36.5	34.6	26.4	5.2	5.9	5.1	5.4	21.5	23.0
Repayments of lines of credit	(32.8)	(39.0)	(28.4)	(4.8)	(5.2)	(7.0)	(8.1)	(25.1)	(36.7)
Contingent consideration Payments	0.0	0.0	(6.4)	0.0	0.0	0.0	0.0	0.0	0.0
Cash from non-controlling interest	0.0	0.0	2.7	0.8	(0.7)	(0.3)	(0.1)	(0.3)	1.0
Net Cash Provided by Financing Activities	6.0	186.2	7.3	13.8	4.7	(0.2)	0.2	18.5	10.3
Effect of exchange rate on cash and cash equivalents	(0.0)	0.1	(0.1)	(1.0)	0.5	(0.5)	(0.5)	(1.5)	(1.0)
Net increase (decrease) in cash	(44.2)	158.4	(88.9)	251.3	(127.0)	(84.5)	4.0	43.7	110.6
Cash at beginning of period	71.5	27.4	185.8	96.9	348.2	221.2	136.7	96.9	140.7
Cash at end of period	27.4	185.8	96.9	348.2	221.2	136.7	140.7	140.7	251.2
**Net loss include net loss from income statement plus effect of exchange rate on cash and cash equivalents								Yale Jen, Ph.D. 212-953-4978	

Source: Bloomberg LP; Company reports; Laidlaw & Company estimate

DISCLOSURES:

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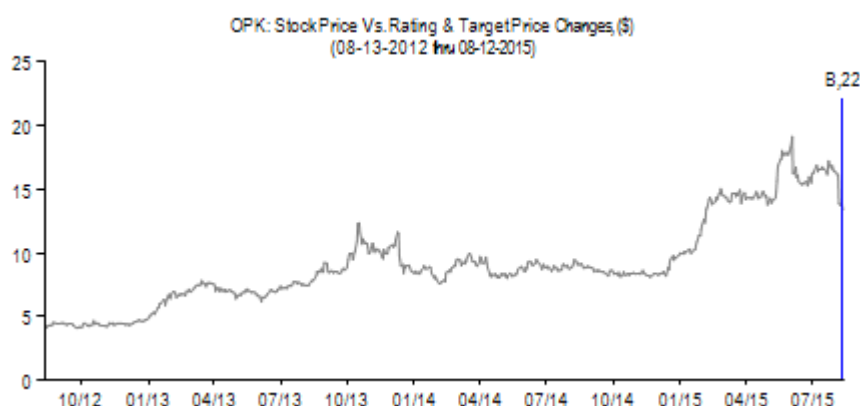
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Additional information available upon request.

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RATINGS INFORMATION

Rating and Price Target Change History



Date	Rating	Closing Price (\$)
08/12/2015	Buy (B)	13.45*

Date	Target Price (\$)	Closing Price, (\$)
08/12/2015	22.00	13.45*

* Previous Close 8/11/2015

Source: Laidlaw & Company

Created by: Blue-Compass.net

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	75.86%	31.03%	6.90%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.45%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Tesaro Inc. (TSRO – Not Rated)
 Pfizer Inc. (PFE – Not Rated)
 Baxalta (BXL – Not Rated)
 Versartis (VSAR – Not Rated)
 Teva Pharmaceutical Industries (TEVA – Not Rated)
 Merck (MRK – Not Rated)
 Novo Nordisk A/S (NOVOB.DC – Not Rated)
 CSL Behring (0007075D – Not Rated)
 Catalyst Biosciences (CBIO – Not Rated)
 ARNO Therapeutics (ARNI – Not Rated)

August 12, 2015

RXi Pharmaceuticals (RXII – Not Rated)
Pharmsynthez (MCX: LIFE – Not Rated)
Cocrystal Pharma (COCP – Not Rated)
Sevion Therapeutics (SVON – Not Rated)
Neovasc (NVCN – Not Rated)
ChromaDex (CDXC – Not Rated)
MabVax Therapeutics (MBVX – Not Rated)
Beckman Coulter (BEC – Not Rated)
Eisai Co., Ltd (TYO: 4523 – Not Rated)

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