

PHOTOCURE ASA BUILDING A SPECIALTY PHARMA COMPANY

RESULTS OF THIRD QUARTER AND
FIRST NINE MONTHS 2015

29 OCTOBER 2015

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PROGRESS ON KEY OBJECTIVES

KEY OBJECTIVES

- Hexvix/Cysview global in-market unit sales growth of 10%
- Submit Special Protocol Assessment Request (SPAR) for Cevira by mid-2015
- Initiate Phase 3 clinical trial to expand the use of Hexvix/Cysview into the surveillance market and fulfill the US post marketing commitments in 2015
- Secure partnership for further development and commercialization of Visonac and Cevira reflecting the product potential

3Q2015 KEY ACHIEVEMENTS

- 8% growth in-market unit sales
- Commercial franchise profitability 9.0 MNOK
- Achieved Special Protocol Agreement for Cevira with FDA
- Patient enrollment initiated October 1
- Discussions continued with potential partners

Significant improvement of Commercial Franchise financial performance (EBIT) with 23.1 MNOK YTD



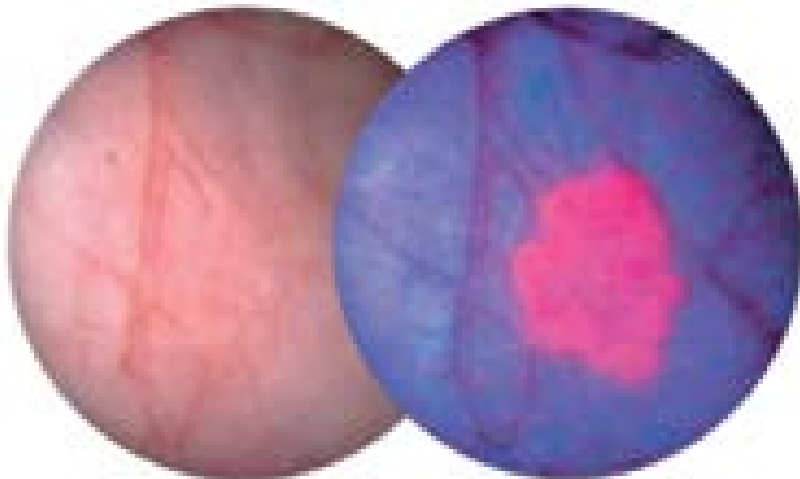
Commercial Update



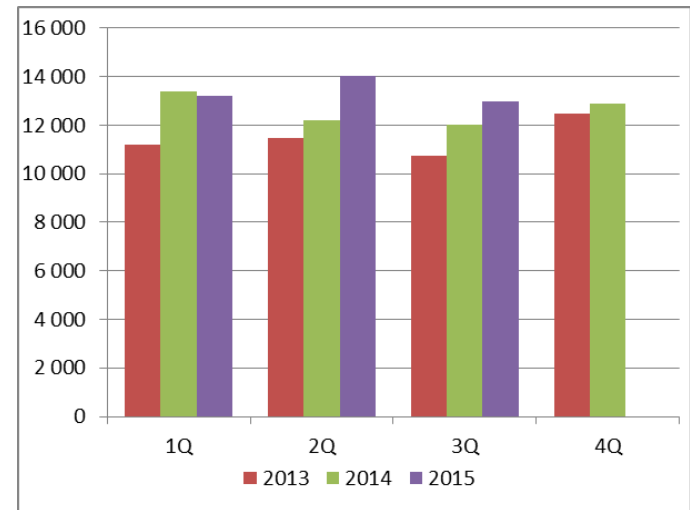
HEXVIX/CYSVIEW

A SIGNIFICANT GLOBAL SPECIALTY BRAND

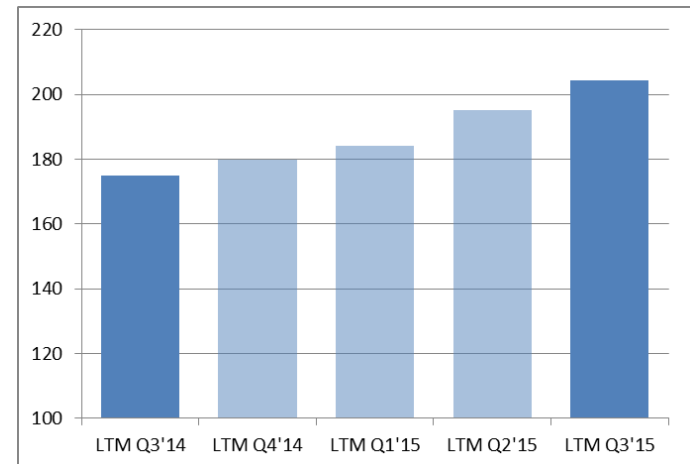
- Value of in-market sales of Hexvix/Cysview increased YoY 19% year to date to NOK 204 million LTM
- Hexvix/Cysview global in-market volume increased YoY 8% in the quarter, and 7% year to date
- Overall franchise EBIT year to date at NOK 23.1 million, improvement of NOK 12.0 million from prior year



Global in-market unit sales (by Q)



Global in-market value NOK mill (LTM)

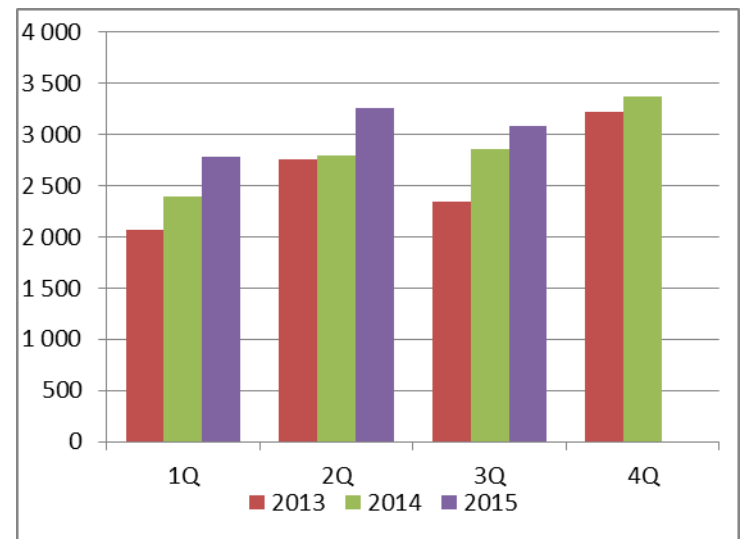


HEXVIX/CYSVIEW

SOLID PERFORMANCE IN NORDICS AND USA

- Photocure own sales revenue in the US and Nordics increased YoY 22% in 3Q and 35% year to date to NOK 42.1 million
- US revenue increased year to date 84%
 - Driven by in-market volume growth of 29%, price increases and FX
 - Permanent Blue Light Cystoscope placements of 62 at the end of 3Q
 - Continued progress on passage of bill to provide separate payment to hospitals for Cysview
- Nordic revenue increased year to date 17%
 - In-market volume growth of 9%
 - Continued double digit in-market volume growth in Sweden

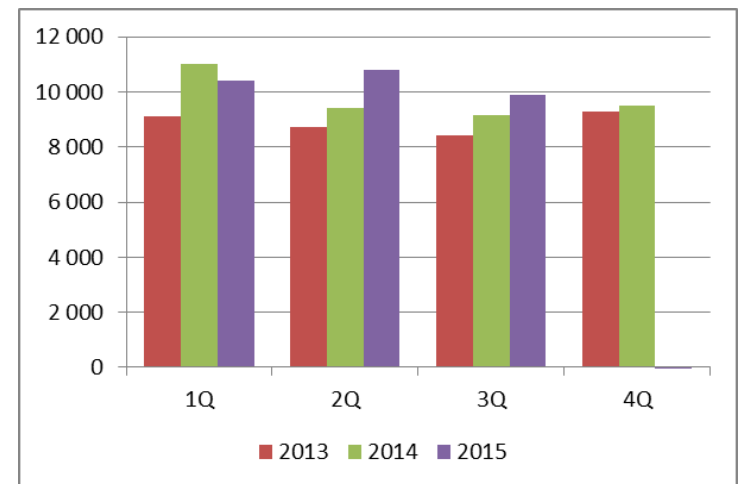
Own Hexvix/Cysview in-market unit sales
Nordic and US



HEXVIX/CYSVIEW PARTNER PROGRESS

- Partner revenue increased 4% in 3Q and 12% year to date to NOK 40.5 million
 - 3Q revenue driven by timing of inventory replenishments in 2014
- End user volume growth 8% in 3Q and 5% year to date
- Double digit unit growth year to date in Germany and France
- Executed distribution agreement with BioSynt Pharma for Cysview in Canada
 - USD 650 000 received at signing, an additional USD 350 000 as later milestones
- Marketing Authorization Application filed in Australia by partner Juno Pharma in September

Hexvix Partner Unit Sales Per Quarter



Pipeline Update



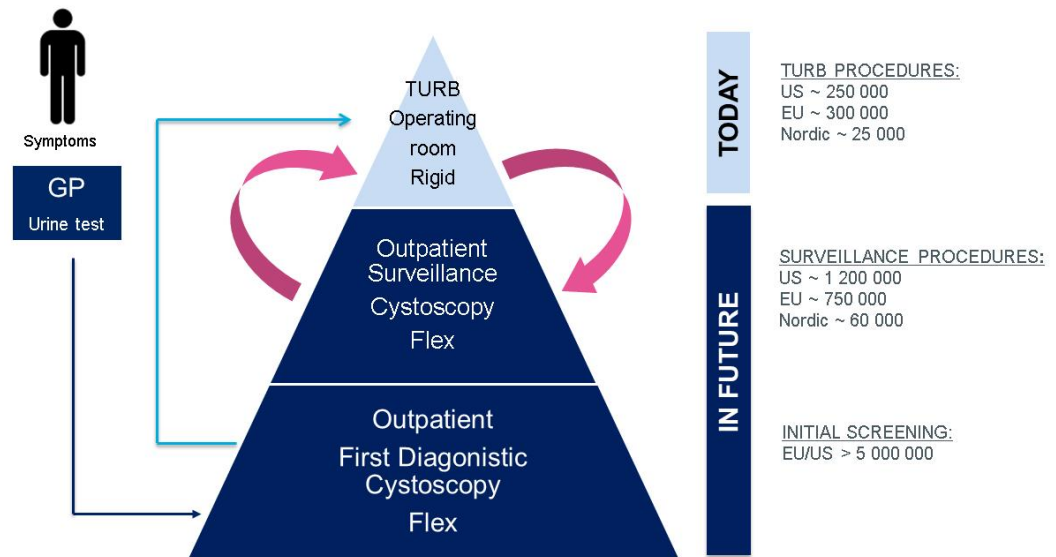
CREATING VALUE CLINICAL DEVELOPMENT PROGRAMS

	Technology	Indication	Phase 1	Phase 2	Phase 3	Status
Cevira®	PDT	Treatment of precursors of cervical cancer				Positive Phase 2b results SPA approved Exploring partnerships
Visonac®	PDT	Treatment of moderate to severe acne				Positive Phase 2b results SPA and PIP approved Exploring partnerships
Hexvix® Cysview®	PDD	Detection of bladder cancer, surveillance segment				First Patient, First Visit in October

HEXVIX/CYSVIEW EXPANDING INTO THE SURVEILLANCE SEGMENT

- Surveillance following initial diagnosis represents a significant growth opportunity of 2-3 times current TURB segment
- First Patient, First Visit in Hexvix/Cysview Phase 3 market expansion study in October
 - Study including 360 patients to examining improved detection rate of Hexvix/Cysview blue light cystoscopy vs white light cystoscopy
 - Study results expected in 2017
 - Secured alignment with FDA on study design necessary to obtain label extension

Global Cystoscopy Market Consists of Three Distinct Market Segments



CEVIRA

A MAJOR OPPORTUNITY

- Breakthrough single use and fully integrated drug-device technology to satisfy high need for novel therapies to treat global epidemic of HPV/CIN populations
 - A well tolerated non-systemic treatment option for patients which preserves fertility and avoids the morbidities of invasive surgery
- Results of the Phase 2b trial are significant
 - Statistically significant HSIL (CIN2,3) regression in the FDA agreed phase 3 patient population ($p=0.004$)
 - Statistically significant virologic clearance of oncogenic HPV at 9 months after first treatment ($p=0.045$)
 - Excellent tolerability and high physician & patient acceptance
- Achieved Special Protocol Agreement with FDA in August for patients with HSIL
 - Alignment on clinical phase 3 program of two similar double blind, placebo controlled studies with 200 patients in each study with primary efficacy end point 6 months after treatment
- Further strengthened patent portfolio with issuance on new patent in EU

Cevira®



ajog.org

RESEARCH

GYNECOLOGY

A randomized study of hexaminolevulinate photodynamic therapy in patients with cervical intraepithelial neoplasia 1/2

Peter Hillemanns, MD; Francisco Garcia, MD, MPH; Karl Ulrich Petry, MD; Vladimir Dvorak, MD; Oliver Sadovsky, MD; Ole-Erik Iversen, MD; Mark H. Einstein, MD, MS

OBJECTIVE: The objective of the study was to investigate the efficacy and safety of hexaminolevulinate (HAL) photodynamic therapy (PDT), a novel therapy for women with cervical intraepithelial neoplasia (CIN) 1/2, to define the appropriate population and endpoints for a phase 3 program.

STUDY DESIGN: This was a double-blind, randomized, placebo-controlled, dose-finding study that included a total of 262 women with biopsy-confirmed CIN 1/2 based on local pathology. Patients received 1 or 2 topical treatments of HAL, hydroxyethylrubicin (0.2%, 1%, 5%, clear dose effect with a statistically significant response in the HAL 5% group of 95% (16/19 patients) compared to 57% (12/21 patients) in the placebo group ($P < .001$) was observed at 1/2, to define the appropriate population and endpoints for a phase 3 program.

3 months in women with CIN2, including an encouraging 83% (6/6 patients) clearance of HPV 16/18 compared to 33% (2/6 patients) in the placebo group at 6 months. The treatment was easy to use and well accepted by patients and gynecologists. Only local self-limiting adverse reactions including discharge, discomfort, and spotting were reported.

by that shows promise in the treatment of HPV, but not of CIN. HAL PDT is a tissue-ablating therapy for patients with CIN 1/2. HAL PDT is a tissue-ablating therapy for patients with CIN 1/2. HAL PDT is a tissue-ablating therapy for patients with CIN 1/2.

Patients with cervical intraepithelial neoplasia

EXPERT OPINION

1. Introduction
2. Treatment review
3. Conclusion
4. Expert opinion

Drug Evaluation

Topical hexaminolevulinate photodynamic therapy for the treatment of persistent human papilloma virus infections and cervical intraepithelial neoplasia

Peter Hillemanns*, Mark H Einstein & Ole Erik Iversen
*Hannover Medical School, Department of Obstetrics and Gynecology, Hannover, Germany

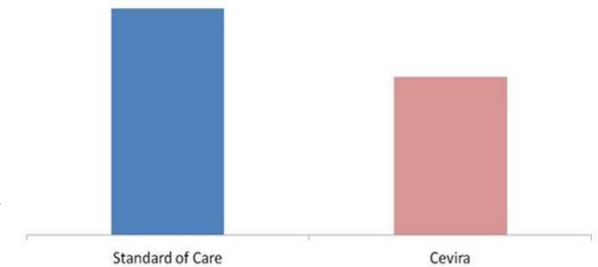


CEVIRA

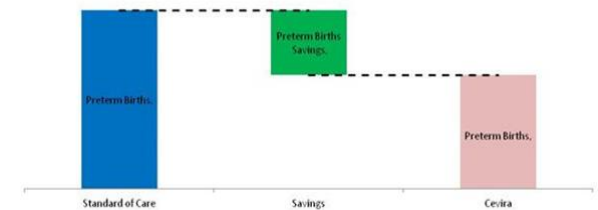
SIGNIFICANT SALES POTENTIAL

- Large patient population based on biopsy confirmed histology of HSIL
 - ~1M cases HSIL annually in US & West EU^{1,2} detected through routine cervical screening programs; 50% of these are caused by HPV strain 16 or 18³
 - ~30% risk of progress to cervical cancer⁴
 - Upside exists in Latin America, Asia and East EU, where burden of HPV is higher
- LCM Opportunity for clearance of oncogenic HPV in patients with normal cytology/LSIL
 - It is estimated that ~35M are HPV infected in US & EU, with a prevalence of HPV strains 16 or 18 of 32% (~11M)
 - 10-15M cases oncogenic HPV annually in US & West EU⁶ detected through routine cervical screening programs
 - Persistent infection occurs in 10-20% of the cases⁷
- Blockbuster sales potential based on premium pricing opportunity
 - At premium price levels, cost impact model demonstrates cost savings / benefit to the US health care system as compared to current treatment practice⁵
 - Additional significant savings when avoidance of costs associated with preterm births factored in⁵
- Continued discussions with potential partners for development and commercialization

Average Cost per patient to screen and treat, 24 months



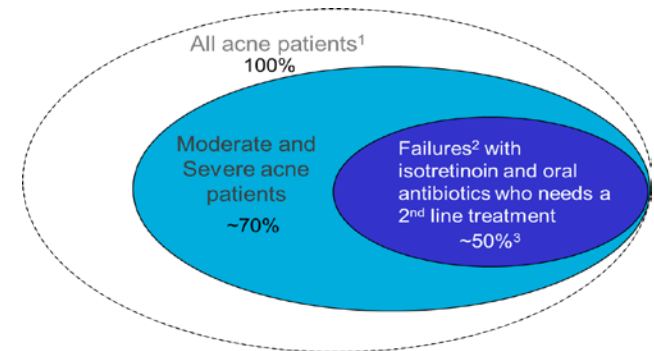
Birth Year Medical Costs, With and Without Cevira



VISONAC

PHASE 3 READY ASSET WITH CONSIDERABLE SALES POTENTIAL

- High unmet need for novel treatments for moderate/ severe acne
- Positive Phase 2b results
 - Significant reduction in inflammatory lesions and improvement of overall acne severity
 - Well tolerated regimen
- Phase 3 Ready with significant reduced regulatory risk
 - SPA (US) and PIP (EU) agreed for global registration program
- Further strengthened patent portfolio with issuance on new patent in EU
- Value of moderate to severe acne pharma market segment estimated at ~\$900 MUSD globally
 - Dermatologist main prescriber of oral antibiotics and retinoids
- Visonac positioned as second line alternative
 - In US and EU, >2M patients in need of second line treatment options
 - Favorable benefit/risk profile compared to existing treatment options and sustained efficacy allows for premium price
- Continued interest from potential partners for development and commercialization



¹Patients who require some form of prescription medicine treatment

²Patients who are unsuitable for, or recalcitrant to, oral antibiotics and/or isotretinoin

³Estimate based on market research among dermatologists



Financials



HEXVIX/CYSVIEW CONTINUED GROWTH THIRD QUARTER 2015

- Revenue from own sales of Hexvix/
Cysview increased YoY 22% in 3Q and
35% year to date
 - Nordic 3Q revenue growth of 11%
 - US 3Q revenue growth of 42%
- Partner 3Q revenue increased YoY 4%
and 12% year to date
 - Changed timing of supply to partner compared
to the same period in 2014
- Total in market sales value increased
YoY 22% in 3Q and 19% year to date
 - LTM value NOK 204 million

<i>SALES - MNOK</i>	Q3 '15	YTD '15
Hexvix - Nordic	8,1	26,4
<i>YoY growth</i>	11 %	17 %
Cysview - US	5,3	15,7
<i>YoY growth</i>	42 %	84 %
Hexvix own sales	13,5	42,1
<i>YoY growth</i>	22 %	35 %
Hexvix partner sales	13,5	40,5
<i>YoY growth</i>	4 %	12 %
Total Photocure	27,0	82,6
<i>YoY growth</i>	12 %	23 %
Revenue in-market (*)	51,2	155,6
<i>YoY growth</i>	22 %	19 %
Units in-market (*)	12 965	40 222
<i>YoY growth</i>	8 %	7 %

(*) Calculated in-market sales

PROFIT & LOSS

THIRD QUARTER 2015

<i>MNOK</i>	Q3 '15	Q3 '14	Change	YTD '15	YTD '14	Change
Hexvix / Cysview revenues	27,0	24,1	12 %	82,6	67,2	23 %
Other sales revenues	2,3	0,8		6,5	1,6	
Signing fee and milestones	6,6	31,9		11,1	34,2	
Total revenues	35,9	56,8	-37 %	100,2	103,0	-3 %
Gross profit	33,9	55,2	-39 %	94,0	97,8	-4 %
Operating expenses	-36,6	-31,4	16 %	-105,8	-93,4	13 %
EBIT	-2,7	23,8		-11,8	4,4	
Net financial items excl PCI	2,8	0,3		4,5	2,5	
Impairment loss shares PCI	-	-		-7,7	-	
Profit/loss(-) before tax	0,1	24,2		-15,0	6,9	
Tax expenses	-5,0	-		-11,8	-	
Net profit/loss(-)	-4,9	24,2		-26,7	6,9	

- Total revenue decrease YoY 37% in 3Q and 3% year to date
 - Driven by termination fee paid by Salix in 2014, NOK 30.8 million
- Operating expenses increase YoY 16% in 3Q and 13% year to date
 - Mainly driven by FX, year to date 2% increase in constant currencies
- Operating loss (EBIT) at NOK 2.7 million in 3Q and NOK 11.8 million year to date

SEGMENTS

THIRD QUARTER 2015

- Commercial franchise:

- Continued improvement in revenues and EBIT
- EBIT margin year to date at 23%

- Development portfolio:

- Activities related to Cevira SPAR
- Cysview post marketing commitment phase 3 capitalized

<i>MNOK</i>	<u>Q3 '15</u>	<u>Q3 '14</u>	<u>YTD '15</u>	<u>YTD '14</u>	<u>LTM</u>
<u>Commercial Franchise</u>					
Total revenues	35,9	26,1	100,2	72,2	126,2
Gross profit	33,9	24,5	94,0	67,1	118,2
Operating expenses	-24,8	-18,8	-70,9	-56,0	-90,2
EBIT	9,0	5,7	23,1	11,1	28,0
<u>Development Portfolio</u>					
Total revenues	0,0	0,0	0,0	0,0	0,0
Gross profit	0,0	0,0	0,0	0,0	0,0
Operating expenses	-11,7	-12,6	-34,9	-37,4	-49,8
EBIT	-11,7	-12,6	-34,9	-37,4	-49,8
<u>Total</u>					
EBIT	-2,7	-6,9	-11,8	-26,4	-21,8
(*) One-Off's excluded					
Salix termination fee		30,8		30,8	0,0

CASH FLOW

THIRD QUARTER 2015

<i>MNOK</i>	Q3 '15	Q3 '14	YTD '15	YTD '14
Cash flow from:				
- Operations	-4,8	25,2	-19,2	-3,2
- Investments	-3,9	0,9	-9,0	2,8
- Financing	1,5	0,0	2,4	0,0
Net change in cash	-7,2	26,1	-25,8	-0,4
Ending cash balance	139,5	166,8	139,5	166,8

- 3Q cash flow from operations NOK -4.8 million, year to date NOK -19.2
 - Year to date improvement of NOK 14.8 million from last year, excluding impact of Salix NOK 30.8 million
- Year to date cash flow from investments NOK -9.0 million.
 - Includes investments of NOK 10.5 million in intangible assets mainly related to the initiation of the phase 3 post-marketing commitment trial for Cysview
- Quarter end cash balance at NOK 139.5 million

BALANCE SHEET

PER 30 SEPTEMBER 2015

- Non current assets includes NOK 8.6 million in shares in PCI Biotech and deferred tax asset of NOK 19.8 million
- No interest bearing debt at quarter end
- Shareholder's equity of NOK 217.7 million
- Equity ratio of 87%
- Photocure held 35,476 own shares at end of quarter

<i>MNOK</i>	30.09 2015	31.12 2014
Non-current assets	71,0	76,5
Inventory & receivables	39,0	28,8
Cash & equivalents	139,5	165,2
Total assets	249,5	270,6
Shareholders equity	217,7	240,1
Long term liabilities	3,7	3,1
Current liabilities	28,1	27,5
Total equity & liabilities	249,5	270,6
Equity ratio	87 %	89 %

Outlook



OUTLOOK

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FINANCIAL

- Hexvix/Cysview global in-market unit sales growth of 10% in 2015

CLINICAL

- Initiate necessary documentation for the Cevira device to ensure readiness for the Phase 3 trial following the SPA approval
- Reporting of clinical results of Hexvix/Cysview phase 3 market expansion study in 2017

PARTNERSHIP

- Secure partnership for further development and commercialization of Visonac and Cevira reflecting the product potential