

## COMPANY NOTE

Estimate Change

USA | Healthcare | Medical Supplies & Devices

May 12, 2015

# Jefferies

EQUITY RESEARCH AMERICAS

## Unilife Corporation (UNIS) Still Waiting on Those Commercial Sales

**BUY**

Price target \$8.00

Price \$3.17

### Key Takeaway

**UNIS reported \$8.9mn in cash receipts and about \$12mm in operating cash burn in 3Q. Recognized revenues remain lumpy (\$2.9mn in 3Q) as all of the activity is still development work; the elusive commercial sales ramp is yet to come. Total cash used was \$16mn, about the same as the last 3 Qs, and UNIS has \$39mn on the books.**

**Burn remains acute.** Customer receipts were \$8.9mn, a good bump from the \$7.2mn last Q, while reported revenue was \$2.9mn. Operating cash burn was \$11.6mn and including about \$4.6mn in investments in PP&E, total operating and investing cash burn was \$16.2mn—about the same as the last three quarters. Following the recent equity raise, the company has about \$39mn in cash. Cash receipts remain entirely development related payments from pharmaceutical partners and are difficult to predict (as is the timing of when receipts are recognized as revenue). The company will continue to spend and operating costs aren't expected to moderate; facility expansion will also continue keeping cap ex in the \$20mn/yr range. UNIS noted that two new manufacturing lines have been built and two more are on order.

**Development roster is unprecedented but where are the commercial sales?** With AbbVie recently joining a roster of blue chip partners, Unilife has no shortage of potential customers. The deals are unprecedented in their breadth and scope and include healthy upfront payments and the promise of substantial and sustained revenues once the deals move to more of a commercial footing. And that move to commercial sales remains the one piece of the story that has yet to gel. The level of commitment by all the parties is clear evidence that progress continues—but until a partner takes commercial product from Unilife, fills it with a drug, and it is used in a clinical setting, there will be room for doubt. The company remains unwilling to commit to when this will happen but for our part, we continue to believe the payoff when these commercial sales finally do kick in is reason for continued patience.

**Adjusting numbers; staying at Buy.** We have adjusted our model modestly, though with little visibility on timing for deal milestones or commercial sales, the model remains a work in progress. Our target is \$8.

### Valuation/Risks

We value the Sanofi deal at \$4 per share (DCF) and the remaining business at \$4 (5x FY17E) for our \$8 target. Risks include cash needs and development timelines.

USD	Prev.	2013A	Prev.	2014A	Prev.	2015E	Prev.	2016E
Rev. (MM)	--	2.7	--	14.7	22.3	15.1	63.9	59.5
<b>EPS</b>								
Sep	--	(0.16)	--	(0.12)	--	(0.21)A	--	--
Dec	--	(0.19)	--	(0.17)	--	(0.18)A	--	--
Mar	--	(0.17)	--	(0.15)	(0.15)	(0.20)A	--	--
Jun	--	(0.13)	--	(0.15)	(0.13)	(0.18)	--	--
FY Jun	--	(0.66)	--	(0.60)	(0.67)	(0.76)	(0.35)	(0.38)

### Financial Summary

Book Value (MM):	(\$19.9)
Book Value/Share:	(\$0.20)
Net Debt (MM):	\$67.5
Long-Term Debt (MM):	\$78.3
Cash & ST Invest. (MM):	\$10.8

### Market Data

52 Week Range:	\$4.90 - \$2.00
Total Entprs. Value (MM):	\$386.7
Market Cap. (MM):	\$319.2
Insider Ownership:	10.1%
Institutional Ownership:	38.0%
Shares Out. (MM):	100.7
Float (MM):	115.8
Avg. Daily Vol.:	1,390,082

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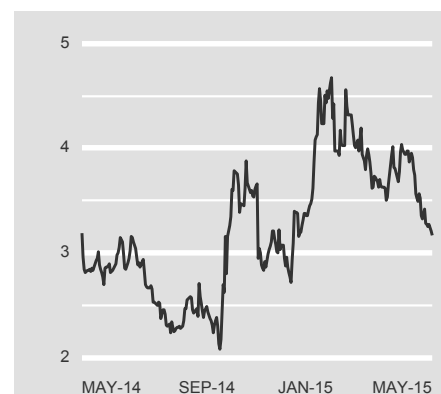
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### Price Performance



**Chart 1: UNIS Known Deals**

Company	AbbVie	"a global pharmaceutical company"	Sanofi	Hikma	Medimmune	Sanofi	Novartis	"a global pharmaceutical company"	"a pharmaceutical company"	"US-based global pharmaceutical customer"
date announced	1/20/2015	12/2/2014	10/6/2014	11/20/2013	11/11/2013	9/9/2013	12/2/2013 (first announced 11/29/2011)	12/16/2013	6/18/2012	7/19/2011
Description of therapeutic	Exclusive use of Finessa and Lisa for Auto-immune diseases	Depot-ject delivery system with an approved ocular injection therapy	Estimated 5 to 10 applicable molecules that will be delivered in wearable injectors	20 generic injectable products	Molecules still in development; several molecules in portfolio will be selected for use (assumed to be 5-10 molecules)	Lovenox	novel Investigational Novartis drug delivered into a targeted organ	a target injectable therapy into the eye	Generic equivalent of an approved auto-immune therapy that is currently available in a standard prefilled syringe format for use across several indications	to conduct drug compatibility and stability tests
Unifile product	Finessa prefilled and LEA reusable auto-injector	Depot-ject	Wearable injector	Customized Unifill	"ReadyToGo" Wearable Injector	Customized Unifill	novel device for targeted organ delivery	Unifile Ocu-ject ocular drug delivery system	Unifill	Unifill
Contract details	AbbVie will pay \$5 million for exclusive right to formulate into exclusive development and supply agreement for auto-immune diseases	a worldwide 10 year Commercial Supply Agreement done for lifecycle management of this approved therapy	Sole provider of wearable injectors to Sanofi for all of its applicable large volume drugs, excluding insulins, for a minimum 15 years  Sanofi has non-exclusive access to Unifile wearable injector technology during the period of the agreement  Unifile maintains the right to sign supply agreements with other customers for wearable injectors	Commercial sales begin in FY14 with minimum 175MM units per year following a rapid high-volume ramp up period.  \$40 million in upfront and milestone payments. \$5 million paid immediately, an additional \$15 million expected during 2014. \$20 million in milestone-based payments paid 2015.  15 year global agreement, granted exclusive global rights, additional drugs can be added	Will initially supply product to Medimmune for clinical trial use	Following a four year ramp-up period after market entry, exclusivity will be maintained, subject to Sanofi purchasing a minimum of 150 million units  \$15m in milestone payments, with \$5m in 2013  Granted exclusive use of Unifill for Enoxaparin Sodium sold under the brand names Lovenox and Cloxane; contract can be extended to 2024	From 12/2 announcement: Unifile will generate revenue on the basis of the clinical product supplies and activities involved in clinical development.  From initial announcement: \$1.4m initial agreement, \$500k realized thru 3Q12, balance in 4Q12	Unifile will begin to generate revenue under the program in January 2014  Not exclusive  Other details not disclosed	Annual volumes for Unifill within the initial European geography expected to reach up to 10mm units during the contract period, generating up to \$15 million in revenue per year.	
Status		Available after a 12 to 24 month process of customization and regulatory approval for the drug-device combination					12/2/13: provided further details  Ready to move to next stage (CY4Q12 call)  4/26/12: ready to ship GMP compliant devices		Initial sales will commence in July 2012; regulatory approvals expected in FY13 after which sales will become more significant	
Notes	Humira and other pipeline autoimmune drugs  Humira patent expires in 2016		average selling price assumed \$20-\$35	Assume \$0.70 per syringe for commercial sales	commercial sales expected to be \$20-\$35 per unit; clinical trial units priced much higher (\$500 or more)	Assume \$0.70 per syringe for commercial sales	customized delivery device, consisting of syringe, needle, tubing, controller and pump, to enable administration of a novel investigational Novartis drug into a targeted organ in clinical trials  Novartis has an option for exclusivity	Ocu-ject provides a tenfold improvement in the precision of delivering doses as small as 10 uL, which helps pharmaceutical customers ensure compliance with dose requirements on the drug label  Therapeutic space includes rheumatoid arthritis, psoriasis, psoriatic arthritis, lupus and Crohn's disease. Cumulative U.S. patient population affected by autoimmune diseases is greater than seven million people and approximately twice that worldwide. The drug has also been shown to be effective for the treatment of several cancers including breast, head and neck, leukemia, lymphoma, lung, osteosarcoma, bladder and trophoblastic neoplasms. Currently, the majority of injections within the auto-immune therapeutic class are self-administered by patients using either a standard prefilled syringe or a conventional auto-injector.		UNIS anticipates \$50m in customization fees related to Sanofi over contract period  5-10 drugs Each trial is 1k-2k patients

Source: Jefferies estimates, Company reports

## Chart 2: UNIS Income Statement

Income Statement  
In Millions, Except Per Share Data  
FYE Jun 30

Jefferies

	F2012 A Jun 30-Jun-12	F2013 A Jun 30-Jun-13	F1Q14 A Sept 30-Sep-13	F2Q14 A Dec 31-Dec-13	F3Q14 A Mar 31-Mar-14	F4Q14 A Jun 30-Jun-14	F2014 A Jun 30-Jun-14	F1Q15 A Sept 30-Sep-14	F2Q15 A Dec 31-Dec-14	F3Q15 A Mar 31-Mar-15	F4Q15 E Jun 30-Jun-15	F2015 E Jun 30-Jun-15	F2016 E Jun 30-Jun-16	F2017 E Jun 30-Jun-17
Recognized Upfront & milestone payments	5.5	2.6	3.2	3.6	1.4	6.5	14.7	1.4	5.4	2.9	5.0	14.7	28.0	30.0
Commercial Product sales & other	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.4	31.5	76.7
<b>Total Revenue</b>	<b>\$5.5</b>	<b>\$2.7</b>	<b>\$3.2</b>	<b>\$3.6</b>	<b>\$1.4</b>	<b>\$6.5</b>	<b>\$14.7</b>	<b>\$1.4</b>	<b>\$5.4</b>	<b>\$2.9</b>	<b>\$5.4</b>	<b>\$15.1</b>	<b>\$59.5</b>	<b>\$106.7</b>
Year-to-Year Growth	-17%	-50%	362%	411%	102%	881%	436%	-56%	51%	111%	-18%	3%	294.5%	79.4%
Cash receipts								0.9	7.3	8.9	11.0	28.2		
Total Cost of Sales	0.6	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	13.5	30.7
<b>Gross Profit</b>	<b>4.9</b>	<b>2.6</b>	<b>3.2</b>	<b>3.6</b>	<b>1.4</b>	<b>6.5</b>	<b>14.7</b>	<b>1.4</b>	<b>5.4</b>	<b>2.9</b>	<b>5.3</b>	<b>15.0</b>	<b>45.9</b>	<b>76.0</b>
Gross Margin on Commercial Sales	89.4%	95.3%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	90.0%	99.8%	57.0%	60.0%
<b>Operating Expenses:</b>														
R&D	23.1	21.7	6.4	7.8	8.0	11.9	34.1	11.0	11.3	13.2	13.0	48.5	50.0	55.0
% of Sales	419.2%	792.9%	200.0%	218.5%	579.8%	181.6%	232.0%	784.0%	209.3%	452.3%	243.0%	321.7%	84.1%	51.6%
SG&A	24.1	26.3	6.5	6.7	6.6	8.0	27.9	8.2	9.5	9.1	9.8	36.6	42.0	45.0
% of Sales	436.5%	960.6%	203.8%	187.6%	480.8%	122.5%	189.7%	585.7%	176.0%	310.0%	183.2%	242.6%	70.6%	42.2%
Depreciation & Amortization	4.0	5.4	1.0	1.0	1.0	1.0	4.1	1.1	1.3	1.2	1.1	4.6	5.0	7.0
% of Sales	72.6%	198.1%	32.6%	28.0%	74.2%	15.4%	27.7%	78.6%	23.2%	40.5%	20.6%	30.8%	8.4%	6.6%
Total Operating Expenses	51.2	53.5	13.961	15.510	15.7	20.9	66.1	20.3	22.1	23.5	23.9	89.7	97.0	107.0
<b>Operating Income</b>	<b>(46.3)</b>	<b>(50.9)</b>	<b>(10.8)</b>	<b>(11.9)</b>	<b>(14.3)</b>	<b>(14.4)</b>	<b>(51.4)</b>	<b>(18.9)</b>	<b>(16.7)</b>	<b>(20.5)</b>	<b>(18.6)</b>	<b>(74.7)</b>	<b>(51.1)</b>	<b>(31.0)</b>
Operating Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-29.1%
<b>EBITDA</b>	<b>(42.3)</b>	<b>(45.5)</b>	<b>(9.7)</b>	<b>(10.9)</b>	<b>(13.3)</b>	<b>(13.4)</b>	<b>(47.3)</b>	<b>(17.8)</b>	<b>(15.4)</b>	<b>(19.3)</b>	<b>(17.5)</b>	<b>(70.0)</b>	<b>(46.1)</b>	<b>(24.0)</b>
EBITDA % of Sales	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-22.5%
Net Interest Expense & Other	(1.2)	(2.1)	(0.5)	(4.4)	(0.8)	(0.9)	(6.5)	(3.3)	(2.7)	(2.6)	(2.5)	(11.1)	5.0	10.0
Earnings (Loss) Before Taxes	(47.5)	(53.1)	(11.2)	(16.3)	(15.1)	(15.3)	(57.9)	(22.2)	(19.4)	(23.1)	(21.1)	(85.8)	(46.1)	(21.0)
Pre-Tax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-19.7%
Income Tax Expense	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Net Income, adj. [1]	(47.5)	(53.1)	(11.2)	(16.3)	(15.1)	(15.3)	(57.9)	(22.2)	(19.4)	(23.1)	(21.1)	(85.8)	(46.1)	(21.0)
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-19.7%
<b>Adjusted EPS</b>	<b>(\$0.68)</b>	<b>(\$0.66)</b>	<b>(\$0.12)</b>	<b>(\$0.17)</b>	<b>(\$0.15)</b>	<b>(\$0.15)</b>	<b>(\$0.60)</b>	<b>(\$0.21)</b>	<b>(\$0.18)</b>	<b>(\$0.20)</b>	<b>(\$0.18)</b>	<b>(\$0.76)</b>	<b>(\$0.37)</b>	<b>(\$0.17)</b>
Year-to-Year Growth	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Diluted Shares Outstanding	68.4	81.3	93.8	95.8	97.8	99.0	96.6	107.0	107.6	118.0	118.5	112.8	125.0	127.0

Source: Jefferies estimates, Company data

## Company Description

York, Pennsylvania-based Unilife is a medical device company focused on the design, development, and supply of a proprietary range of retractable safety syringes and other drug-delivery devices including ready-to-fill lyophilized safety syringes, autoinjectors, and autoinfusors.

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Jefferies Group LLC makes a market in the securities or ADRs of Sanofi.

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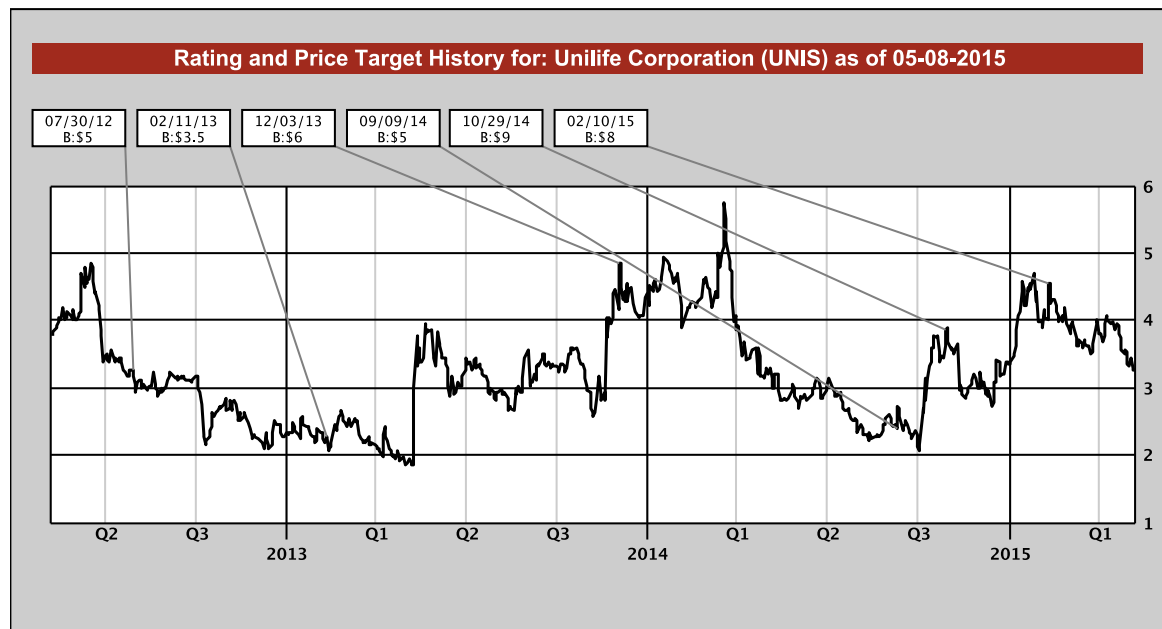
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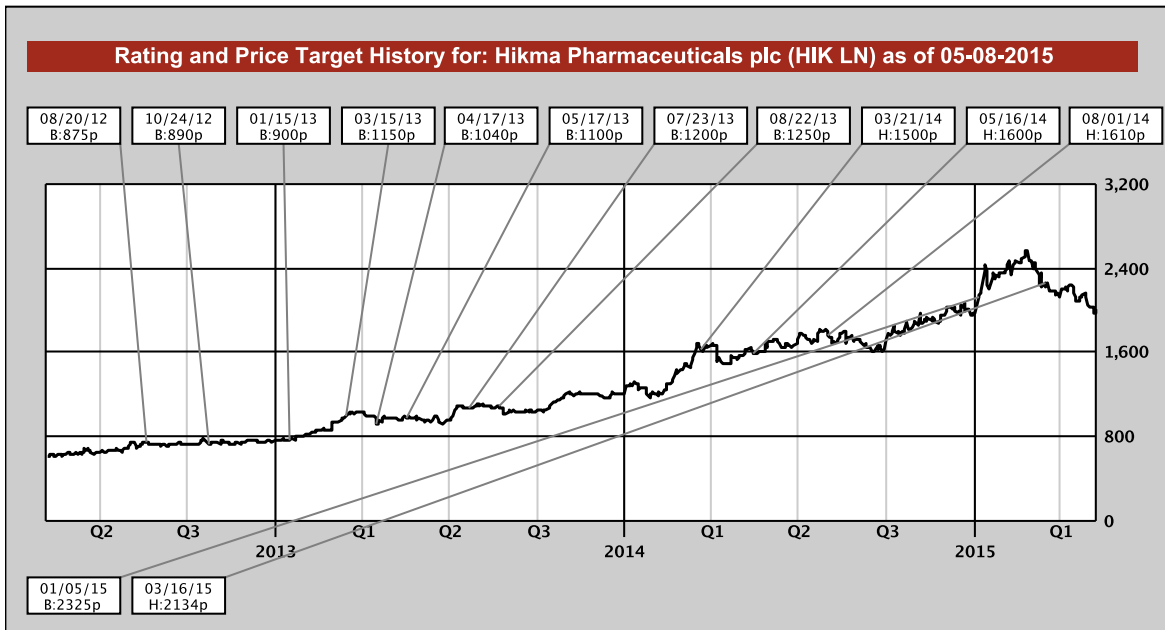
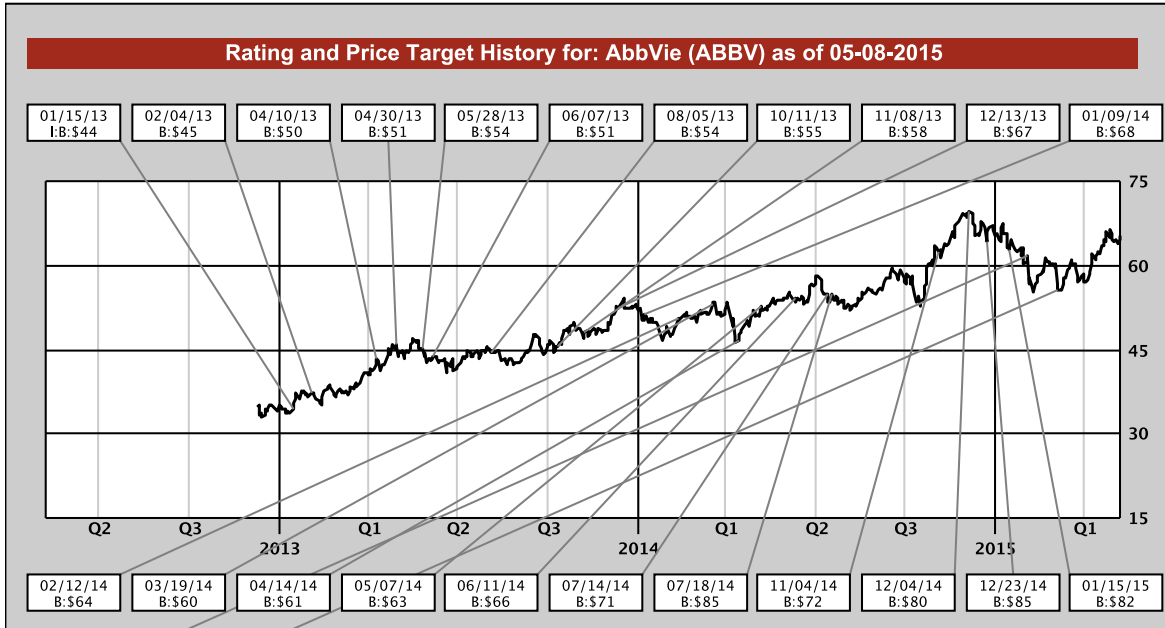
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## Other Companies Mentioned in This Report

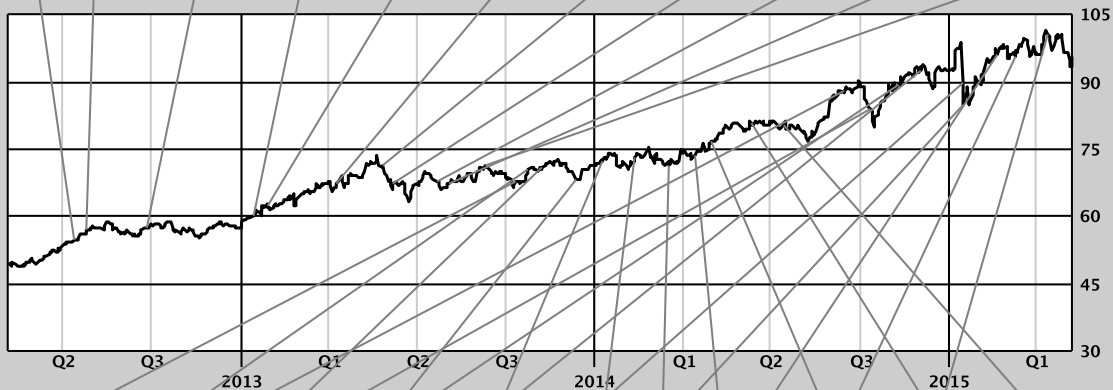
- AbbVie (ABBV: \$65.20, BUY)
- Hikma Pharmaceuticals plc (HIK LN: p2,054.00, HOLD)
- Novartis AG (NOVN VX: CHF95.70, BUY)
- Sanofi (SAN FP: €88.93, HOLD)





Rating and Price Target History for: Novartis AG (NOVN VX) as of 05-08-2015

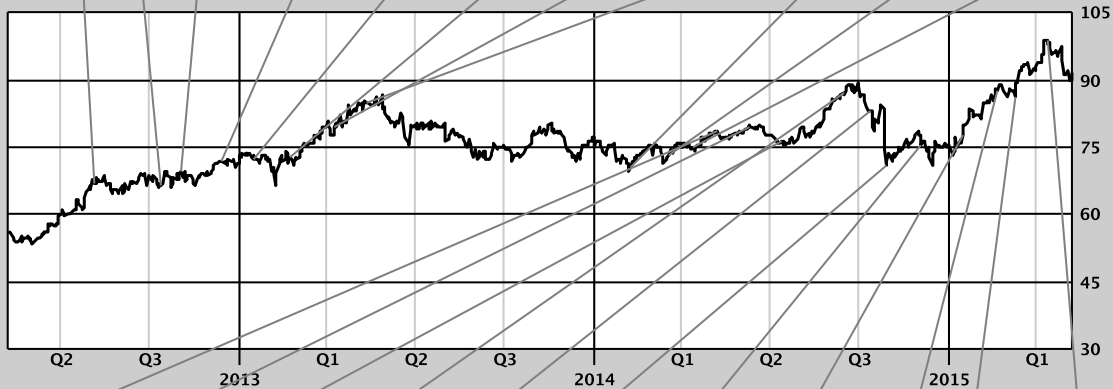
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10/11/13 B:CHF77    10/25/13 B:CHF78    11/08/13 B:CHF80    12/13/13 B:CHF78    01/09/14 H:CHF78    02/12/14 H:CHF76    03/19/14 H:CHF75    04/14/14 H:CHF78    05/02/14 B:CHF87    06/11/14 B:CHF91    07/14/14 B:CHF94

Rating and Price Target History for: Sanofi (SAN FP) as of 05-08-2015

08/06/12 H:EUR68    10/12/12 H:EUR70    11/02/12 H:EUR73    12/14/12 B:EUR82    01/15/13 B:EUR83    02/22/13 B:EUR85    04/10/13 B:EUR88    05/13/13 B:EUR100    02/07/14 B:EUR85    03/19/14 B:EUR83    04/14/14 B:EUR85



05/07/14 B:EUR87    06/11/14 B:EUR90    07/14/14 B:EUR87    09/15/14 B:EUR96    10/13/14 B:EUR97    10/29/14 H:EUR75    12/04/14 H:EUR81    01/15/15 H:EUR80    02/20/15 H:EUR92    03/10/15 H:EUR95    04/13/15 H:EUR101

Distribution of Ratings

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY	1065	51.30%	290	27.23%
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