August 11, 2014

OUTPERFORM

Reason for report:

INITIATION

Dan Leonard
(212) 277-6116
Dan.Leonard@Leerink.com

Justin Bowers, CFA
(212) 277-6066
Justin.Bowers@Leerink.com

LEERINK

ROKA BIOSCIENCE, INC.

Food Pathogen Pure Play; Initiate at Outperform

• **Bottom Line:** We are initiating coverage on ROKA with an Outperform rating and a $13 price target. We believe the company's differentiated technology for food pathogen testing and endorsement by leading contract testing labs and food processors augers well for future revenue growth, growth which is not appropriately captured in the current valuation.

• **Large market opportunity; ROKA poised to take share.** We see ample runway for ROKA to penetrate the ~$225M North American molecular pathogen testing market due to the advantages offered by its Atlas instrument (accuracy, automation, speed) versus legacy molecular testing techniques.

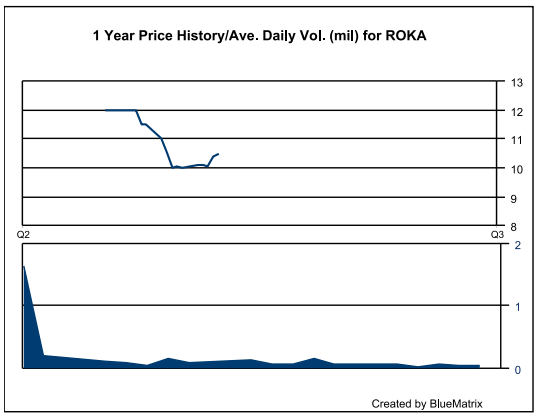
• **Proven testing platform mitigates technology risk.** ROKA's Atlas testing method has already been commercialized in food testing and is widely validated in the field of clinical diagnostics, which we believe mitigates any technology risk commonly associated with early stage companies.

• **Industry trendsetters likely to produce halo effect.** Early adopters of ROKA's technology include the largest food testing contract labs and well-known food processors. In addition, the FDA has purchased an Atlas instrument.

• **Increased globalization, outbreaks, and regulation are secular tailwinds.** We see several secular trends in the food industry that should drive demand for greater testing, including the increase in imported food; the increasing number and magnitude of food recalls; consumer demand for safe food; and increasing regulation.

• **Uncertainty over the slope of the revenue ramp is the primary risk.** While we are confident ROKA will gain share in food pathogen testing over time, the uncertain slope of adoption is the greatest risk to the story. The food industry has a reputation for being cautious, conservative, hesitant to change, and price sensitive. Thus, we believe ROKA's sales process can be long.

Key Stats:	**(NASDAQ:ROKA)**
S&P 600 Health Care Index:	**1,281.24**
Price:	**$10.49**
Price Target:	$13.00
Methodology:	EV on~7.5x revenue for 12-mo ended Jun-16
52 Week High:	$13.00
52 Week Low:	$9.15
Shares Outstanding (mil):	17.6
Market Capitalization (mil):	$184.6
Book Value/Share:	$4.06
Cash Per Share:	$3.90
Net Debt to Total Capital:	NM
Dividend (ann):	$0.00
Dividend Yield:	0.0%



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2013A	$0.3	$0.7	$0.6	$0.7	$2.2	($0.85)	($0.72)	($1.19)	($0.84)	($3.60)	NM
2014E	$0.8A	$1.4	$2.1	$3.8	$8.1	($0.70)A	($0.73)	($0.51)	($0.45)	($2.40)	NM
2015E	--	--	--	--	$24.4	--	--	--	--	($1.42)	NM
2016E	--	--	--	--	$45.2	--	--	--	--	($0.92)	NM

Source: Company Information and Leerink Partners LLC Research
Revenues in $MM, GAAP EPS, IPO priced 7.17.14

INVESTMENT THESIS

We are initiating coverage on Warren, New Jersey-based ROKA Bioscience (ROKA) with an Outperform rating and a $13 price target. ROKA is a commercial stage company whose molecular technology platform differentiates itself from legacy food safety testing methods. The company has forged customer relationships with some of the largest food companies, contract food testing labs, as well as regulatory bodies. We believe early adoption by sector trendsetters and secular tailwinds are positive signposts for the company's growth prospects.

INVESTMENT POSITIVES

Proven Platform, Large Market Opportunity, Secular Tailwinds, Attractive Business

Large market opportunity and poised to take share. We see ample runway for ROKA to penetrate the $2B global food testing market, comprised of pathogen testing, indicator organism testing, and chemical contaminants testing. ROKA's initial focus is the North American molecular pathogen testing market, which we size as a $225M opportunity growing ~10% annually. We believe ROKA is poised to take share in this market due to the advantages offered by its Atlas instrument (accuracy, automation, speed) versus legacy molecular testing techniques. Also, we believe ROKA's development of the mini-Atlas instrument, a lower-volume version of the Atlas, would be embraced by food labs with lower throughput requirements. Our model includes a commercial installed base of 320 and 80 Atlas and mini-Atlas, respectively, by 2018-end.

Proven testing platform mitigates technology risk. ROKA has already commercialized its platform technology (licensed from Gen-Probe) for foodborne pathogen detection and owns the licensing rights for other industrial applications. The company's Atlas instrument is a fully automated platform that generates workflow and cost efficiencies compared to traditional and other molecular (PCR) food testing methods. The Atlas assay menu currently includes tests for five pathogens which cover 98% of commercial pathogen testing volume, and has been validated by an industry accrediting body. The clinical market has already endorsed the underlying benefits of the technology by virtue of Gen-Probe's installed base of 1,200 instruments and approximately 2/3 share of the U.S. market for chlamydia/gonorrhea testing.

Industry trendsetters likely to produce halo effect. Early adopters of ROKA's technology include the largest food testing contract labs and well-known food processors. In addition, the FDA has purchased an Atlas instrument in order to validate the Atlas assays for routine regulatory testing of samples collected by field-based inspectors. We view utilization of the Atlas platform by industry leaders as a positive signpost for greater market penetration. We also believe the FDA's use could spur broader adoption industry-wide.

Increased globalization, outbreaks, and regulation are secular tailwinds. We see several secular trends in the food industry that should drive demand for greater testing, including the increase in imported food; the increasing number and magnitude of food recalls; consumer demand for safe food; and increasing regulation, including the Food Safety Modernization Act (FSMA), whose regulations are being crafted and will be implemented over a multi-year period. Our discussion with a regulator strengthens our conviction that the legislation will lead to an

increase in pathogen testing, and we also find it likely that the FDA will increase its current number of Regional and/or District labs especially for imported food testing.

INVESTMENT RISKS

Pace of Revenue Ramp is Greatest Uncertainty

Revenue ramp is the greatest question. The pace of revenue growth is the greatest uncertainty in our opinion. The food industry has a reputation for being cautious, conservative, and hesitant to change. Food producers also operate on thin margins (low-single-digit operating margins are not uncommon) and thus are very price sensitive. ROKA tests are more expensive on a per-sample basis versus competing molecular test methods. Thus customers need to be sold on total value analysis, which we believe frequently must be accomplished on a case-by- case basis, entailing a longer and more consultative sales process.

Dearth of peer reviewed research could slow near-term adoption. There exists little peer reviewed research that compares molecular testing platforms for the food safety testing market. We view this as a potential impediment to near-term Atlas adoption since customers weigh heavily parameter performance (i.e., sensitivity, specificity) to make platform purchasing decisions. The challenge is compounded by the longstanding ties food labs have to existing testing methods. While ROKA has produced data showing Atlas' benefits over other pathogen testing methods, discussions with industry participants indicated that the food testing industry would be more apt to embrace a new testing technology with peer reviewed literature that compares hundreds of isolates across testing platforms.

Competition from existing and emerging players. The food testing market is highly competitive. Many of whom we view as ROKA's most direct competitors have much larger instrument installed bases, larger sales forces, and broader product offerings than does ROKA. We estimate the installed base for bioMerieux's VIDAS at >4,000 worldwide and DuPont's BAX system at ~1,000 for foodborne pathogen testing applications. Additionally, cost conscious customers have in some instances turned to home-brew testing, whereby they purchase basic instruments and raw reagents from molecular biology vendors and develop their own tests. Nonetheless, we believe that the advantages of the Atlas platform will continue to take share from immunochemical and other molecular methods.

Customer and supplier concentration. ROKA has very high customer concentration, which is not unexpected, given the early stage of its commercialization efforts. The company's top four customers accounted for 82% of ROKA's revenue at the quarter-ended March 31, 2014. We expect this customer concentration will diminish over time. Nonetheless, the loss of one of these customers would materially impact revenue in the near-term. In addition, ROKA purchases its Atlas instruments from Gen-Probe, which sub-contracts Atlas manufacturing from a sole-source supplier that meets FDA and the International Organization for Standardization (ISO) standards governing diagnostic medical device products. Impaired relationships across this supply chain, or the failure of the sole source supplier to maintain compliance with FDA and ISO standards could delay or impact ROKA's ability to deliver products to customers.

COMPANY PROFILE

Molecular Food Safety Testing Pure Play

ROKA Bioscience is currently a pure-play food testing company in one of the higher growth applied markets for life science technology. The company's molecular-based testing platform intends to displace conventional food testing methods. ROKA's value proposition is to provide a suite of solutions that improve accuracy, throughput, workflow, and cost efficiency of food-testing for food producers/processors and contract testing labs. The company was founded in 2009 as a spin-off of the industrial application market assets of Gen-Probe, possesses a worldwide license to Gen-Probe's proprietary molecular assay technology, and licenses access to its fully automated instruments for use in industrial applications.

ROKA generated commercial revenue in 2013 (mostly) and has grown rapidly since then. The 36 Atlas systems placed commercially through 2Q14 have been to the largest food plant labs and contract testing labs, as well as regulatory bodies. The company offers assays for pathogens that collectively represent 98% of the pathogen testing performed by food processors and third-part contract testing labs.

As of June 30, 2014, ROKA employed 121 full-time employees, including: 44 in sales, marketing and commercial operations; 28 in R&D; 28 in manufacturing; and, 21 in general and administrative functions. The company is headquartered in Warren, New Jersey and leases a 45,000 square foot facility in San Diego, California for R&D and manufacturing operations. The latter has significant capacity for expansion.

CHALLENGES IN FOOD TESTING ARE MANY

Many Matrices, Many Demands

We consider the food testing market comparatively more complicated than clinical diagnostics. While clinical diagnostic samples are sourced from blood, stool, urine, or sputum, there are many more relevant matrices (i.e., food samples) in food testing, e.g., orange juice, ground beef, chicken, turkey, spices, seeds, lettuce, cabbage, watermelon, etc., and an assay must be validated for all intended purposes.

Food Matrices are Numerous and Diverse

Source: Marshfield Food Safety, LLC

This wide variation in food matrices equals wide variation in fat content, pH, salt, preservatives, and other inhibitors to traditional molecular testing; thus, all of these assays require matrix-specific optimization. Sample concentration is another distinguishing property of the food testing market. With clinical diagnostics, pathogens are typically present at high concentrations in symptomatic patients. Food testing demands the detection of one pathogenic cell in a food sample (25g – 375g), so the surveyor must enrich the sample. These demands pose numerous analytical challenges. For example, raw foods tend to contain high background of non-pathogenic bacteria, creating a lot of noise in the enrichment. Processed foods have lower background but cells are often stressed or injured, making them difficult to enrich.

ROKA OFFERS SOLUTION

Novel Molecular Food Testing Platform

ROKA provides a comprehensive molecular testing solution for the detection of foodborne pathogens under a razor/razor blade model. The company's Atlas instrument is a fully automated platform that is more accurate and enables workflow and cost efficiencies compared to other food testing methods such as culture, immunoassay, and molecular/polymerase chain reaction (PCR). The Atlas assay detection menu currently consists of five pathogens which cover 98% of commercial pathogen testing volume. These pathogens are: salmonella, listeria, listeria monocytogenes, E. coli 0157:H7, and shiga toxin-producing E. coli (STEC). The Association of Analytical Communities (AOAC) has validated all assays, which means the ROKA method is accredited to test foodborne pathogens in ISO 17025 labs. The following table lists both ROKA's assays and the associated matrices for which these assays are validated.

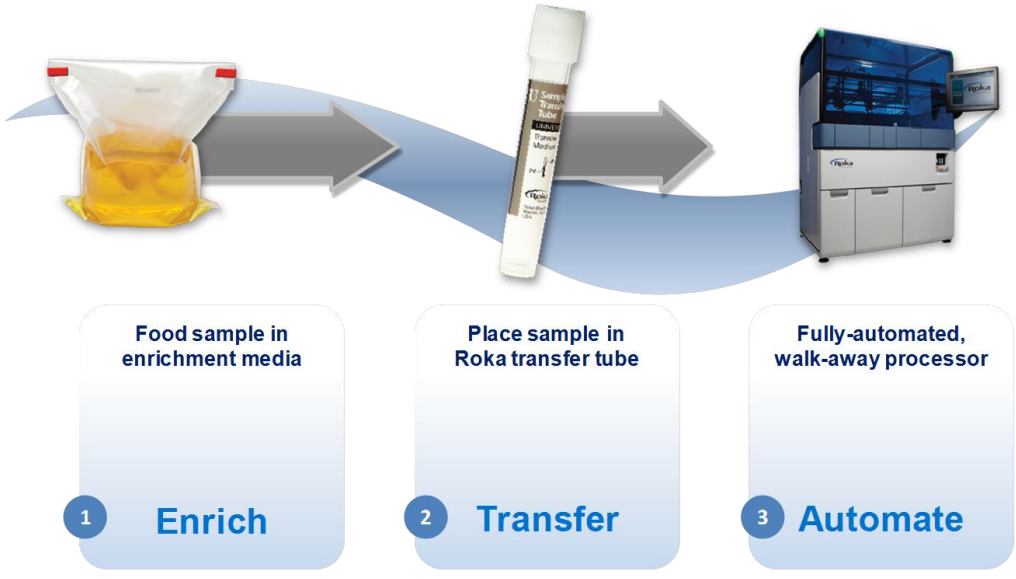
ROKA's Foodborne Pathogen Testing Kits

Method Name	Target Organism(s)	Validated Matrices
Atlas Salmonella Detection Assay	Salmonella enterica	Fresh raw ground beef, frozen raw ground beef, raw ground chicken, cooked deli turkey, cooked deli chicken, pasteurized dried whole egg, raw cod, creamy non-organic peanut butter, romaine lettuce, tomatoes, instant nonfat dry milk, string cheese (mozzarella), milk chocolate, cocoa powder, raw cookie dough, dry pet food, dry pasta, shell eggs, nacho cheese seasoning, black pepper, soy flour, environmental surfaces (stainless steel, plastic, sealed concrete)
Atlas Salmonella G2 Detection Assay	Salmonella enterica	Fresh raw ground beef, fresh raw ground turkey, cooked deli turkey, romaine lettuce, oat cereal, environmental surfaces (stainless steel, plastic, sealed concrete)
Roka Listeria Detection Assay	Listeria spp.	Pasteurized whole milk, ice cream, Brie cheese, hot dogs, cured ham, deli chicken, chicken salad, cold-smoked salmon, romaine lettuce, environmental surfaces (stainless steel, sealed concrete, plastic)
Atlas Listeria monocytogenes LmG2 Detection Assay	Listeria monocytogenes	Hot dogs, cured ham, deli turkey, chicken salad, environmental surfaces (stainless steel), frozen chocolate cream pie, frozen cheese pizza, vanilla ice cream
Atlas E. coli EG2 Detection Assay	E. coli O157:H7	Fresh raw ground beef, fresh raw beef trim, romaine lettuce
Atlas STEC EG2 Combo Detection Assay	E. coli O157:H7 & non-O157 STEC	Fresh raw ground beef, fresh raw beef trim, romaine lettuce

Source: United States Dept of Agriculture (USDA) Food Safety & Inspection Service (FSIS)

Our discussions with customers and consultants (both MEDACorp and otherwise) suggest the ROKA method is well suited to address the challenges in the food testing market. The Atlas instrument is more automated than competing platforms, the sample prep integrated, and the mechanics of ROKA's transcription mediated amplification (TMA) chemistry enable its assays to be faster than more accurate than traditional PCR. The three-step workflow Atlas system requires significantly less labor time, process steps, and manual touches compared to other testing methods. As the following exhibits illustrate, the Atlas workflow requires fewer steps than the PCR method.

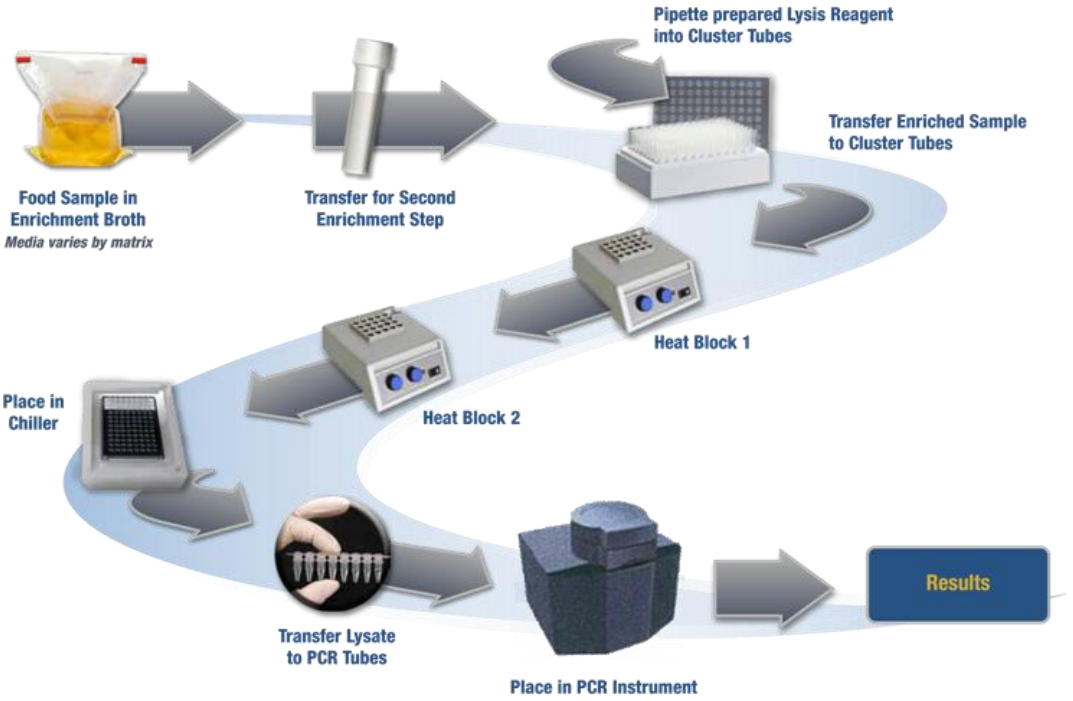
Atlas System Improves Workflow Compared to Other Methods



Source: ROKA

Competing molecular pathogen test methods are complex and may require up to approximately 40 process steps and up to approximately 30 manual touches per sample for a typical PCR-based method. The exhibit blow shows the workflow for a commonly used molecular PCR-based pathogen detection method.

Workflow for Alternative Molecular Testing Method (PCR)



Source: ROKA

ROKA's Atlas method also boasts advantages in accuracy, automation, and speed to result compared to traditional molecular testing methods. We illustrate some of this data in the following tables. While all of the following illustrations were furnished by ROKA, we'll note that the conclusions were directionally consistent with our feedback from customers and consultants.

ROKA has been shown more accurate than molecular (PCR) in comparator studies, with fewer false positives and false negatives; the following table illustrates results from ROKA vs. PCR assays for salmonella and listeria on 580 samples representing 15 different matrix types.

Comparison of Error Rates, Atlas vs. PCR

Error rate	Atlas	PCR
False Positive	0.0%	3.2%
False Negative	1.0%	18.4%

Source: ROKA. Note: These studies were performed on fifteen sample types, which are widely known to be challenging food matrices: ground poultry, poultry rinses, yeast powder and egg products (dried egg white, dried egg yolk, frozen salted egg yolk, frozen liquid sugar yolk, frozen liquid whole egg and liquid egg whites), environmental swabs, deli turkey, fresh mozzarella, cantaloupe, frozen waffles and hummus. Challenging matrices have inherent

characteristics known to result in invalid or false negative results on PCR-based methods, due to the presence of high background flora, fat content, particulate matter, color or sanitizer content.

The ROKA tests have also been shown to yield results more quickly than PCR. This enables faster operational response to pathogen outbreaks with potential to reduce working capital needs and increase shelf life for perishable products. The time to results set forth in the following table include the sum of the enrichment times and actual test time.

Comparison of Time to Results (hours), Atlas vs. PCR

Pathogen	Atlas	PCR	Δ Atlas vs. PCR
Listeria	27	44	17
Salmonella	19	29	10
E. coli O157:H7	14	10	(4)

Source: ROKA. Note: Listeria time to results based on an environmental sponge sample; Salmonella time to results based on a 25g processed grain sample; and, E. coli O157:H7 time to results based on a 375 g ground beef sample.

Actual time to results of course may vary based on sample type, and the differences illustrated in the preceding table do suggest a greater speed advantage for listeria and salmonella than some of our diligence would support. Nonetheless, our diligence is directionally consistent with these claims. We believe faster time to result is a key focus of ROKA's development efforts, and its next generation tests for various pathogens should be even faster.

Finally, the Atlas system is unquestionably more automated than competitive molecular methods, requiring less operator interaction and manual touches. Its automation enables higher throughput, improved accuracy, and reduced labor costs.

Comparison of Operating Metrics, Atlas vs. PCR

Operating metric	Atlas	PCR	% Decrease
Labor time (min)	6	11	(45%)
Process steps (n)	16	33	(52%)
Manual touches (n)	13	22	(41%)

Source: ROKA. Note: The labor time per sample was determined through observation at a ROKA customer site. The process steps and manual touches per sample were determined through a review of product pamphlet inserts for Atlas and PCR.

Labor savings is an important consideration for ROKA's customers, as labor can comprise >40% of total test cost.

While ROKA has produced data showing Atlas' benefits over other pathogen testing methods at specific customer sites, we acknowledge that there exists little peer-reviewed research that compares molecular testing platforms in the food safety testing market.

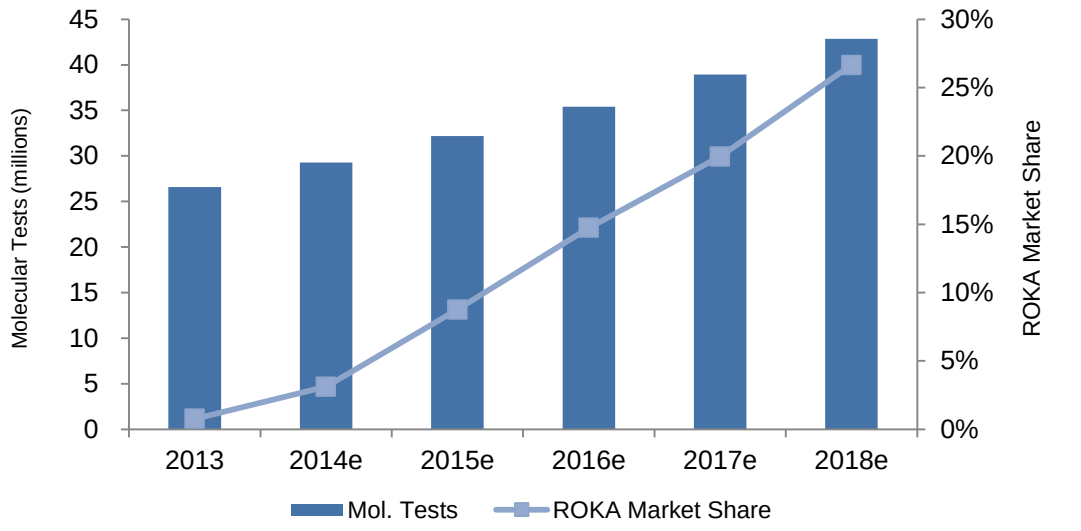
PLENTY OF GROWTH RUNWAY WITH EXISTING PRODUCTS

Atlas Penetration is Early Days; Pipeline Expands Opportunity

We envision several growth drivers for broader adoption of ROKA's technology including company-specific initiatives and secular tailwinds. These drivers form the backbone of our growth

forecasts, which assume ROKA increases market penetration from 3% in 2014 to 27% by 2018 in the rapidly growing North American molecular food pathogen testing market. We size this market at roughly 27M tests in 2013, which equates to a ~$225M market opportunity at ROKA's pricing. We project that this market will grow at a 10% CAGR over the next several years.

North American Molecular Food Pathogen Testing Market and ROKA Market Share



Source: Capella Advisors, ROKA, Leerink estimates.

While we feel comfortable that ROKA could capture >25% of the North American molecular pathogen testing market by for several reasons. The company's existing product offering already includes all the products needed to attain this goal, and thus we are not making any assumptions on forthcoming product development. As noted previously, ROKA's existing menu includes tests that comprise 98% of industry pathogen testing volume. Secondly, early adopters of ROKA's technology include the largest food testing contract labs (e.g., Silliker, Marshfield Food Safety, PrimusLabs, MVTL Labs) as well as food producers (e.g., General Mills, Cargill Meat Solutions, Tyson Foods). Our diligence has confirmed that these labs and food producers are trend setters in the food safety industry, and adoption among this group could serve as a tipping point to broader adoption. Additionally, government bodies including the U.S. Department of Defense Food Analysis and Diagnostic Laboratory (FADL), and the FDA have purchased Atlas instruments. Finally, we are comforted that ROKA's technology has already won against alternative molecular methods in a different market. Gen-Probe's ability to capture 2/3 of the U.S. molecular chlamydia/gonorrhea testing market, despite lack of first mover advantage, serves as testament. The food industry is different than the clinical diagnostics industry to be sure, but we feel we have adequately accounted for these differences in our ramp assumption.

What we lack in our ROKA modeling though is a good set of precedent product adoption curves in the food industry. These analogies don't exist, but we did find some examples that we believe support our growth forecast. The growth trends in mass spectrometry for food, agriculture residue, pesticide, and microbial testing applications could serve as reasonable growth proxies for molecular food testing given the recent adoption of mass spec for these tests. Since 2010 the

forecasted CAGRs for ICP-MS, GC/MS, Quadrupole LC/MS, and MALDI-TOF markets are 14%, 7%, 7%, and 6% through 2014E according to Instrument Business Outlook, 2010-2014. Each mass spec technology addresses at least one of the aforementioned testing applications, and we believe that these applications have motivated growth for mass spec adoption at rates higher than the category averages.

In addition, food safety testing has consistently been one of the fastest growing product lines within 3M's Health Care business segment. While 3M generally does not disclose results at the product level, the Health Care segment has grown in the mid-single digits organically since 2012. We find it reasonable to assume that food testing has been growing above the mid-single digit rate in the broader Health Care portfolio since 3M has consistently cited food testing as a leading growth driver. Additionally, 3M introduced and received AOAC certification for its Molecular Detection System in August 2013. Industry diligence has suggested that the company has placed >100 instruments globally thus far, which to us serves as an encouraging anecdote of new product adoption in food testing.

PIPELINE SHOULD EXPAND MARKET OPPORTUNITY

Non-Amplified Assays, Mini-Atlas Highlight Development Effort

ROKA's development pipeline should yield incremental growth opportunities. We expect its first non-amplified assay introductions could occur in 2015 and enable ROKA to better compete with lower cost immunoassay testing. We believe the company could launch its mini-Atlas instrument in by 2017, which would provide a vehicle for the company to better serve smaller food processors and labs, which far outnumber those with sufficient volume to justify an Atlas. Additionally, the mini-Atlas could prove the vehicle for Roka's eventual international expansion, as labs outside the U.S. tend to be smaller and testing more disseminated. Finally, we expect ROKA will target other horizontals in food testing, the first of which could be chemical contaminant testing (perhaps a 2017/2018 launch). We discuss each of these opportunities below:

- ***Non-amplified assays***: ROKA is developing non-amplified molecular tests to detect the presence of Salmonella and Listeria pathogens. This method would likely compete with immunochemical methods which comprise more than 1/3 of the global food pathogen testing market on a dollar basis. These assays will offer a lower cost alternative to ROKA's existing amplified assays though at the expense of speed to result. Both types of assays will run on the Atlas instrument, which could allow customers to consolidate different test methods on a single platform. ROKA plans to launch the non-amplified versions of its Atlas assays in 2015. The following table highlights what we expect will be the comparative attributes of the two options.

Comparison of Amplified NAT and Non-Amplified NAT Assays

	Product Attributes	
Assay Metrics	Amplified NAT	Non-Amplified NAT
Accuracy	Roka molecular	Roka molecular
Time to Results	Faster or equal to PCR	Similar to immuno
Automation	Sample to result	Sample to result
Cost per Test	PCR + labor savings	Immuno + labor savings

Source: ROKA, Leerink; NAT = nucleic acid testing

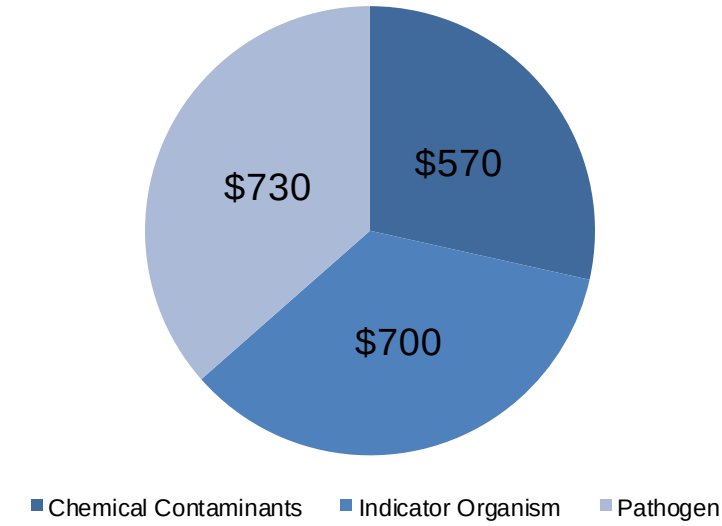
- ***Mini-Atlas instrument***: ROKA is also developing of a lower throughput version of the Atlas instrument (mini-Atlas). The target market would be labs doing less than 75 tests per day, a market segment which comprises the vast majority of food labs globally. The instrument is being developed to have similar operating performance of the Atlas save throughput capacity. This instrument will likely be ROKA's lead offering when it pursues international expansion in food testing, as well as any expansion into other industrial applications. We believe ROKA could launch the instrument by 2017 and have conservatively forecasted an installed base of 80 mini-Atlas by the end of 2018.
- ***Entry into Other Testing Horizontals:*** ROKA is exploring opportunities to develop or acquire technologies and products that address adjacent and complementary segments of the food safety market, such as chemical contaminant testing. Specifically, the company has begun preliminary research work with respect to developing assays for the detection of allergens and mycotoxins.

MARKET OVERVIEW

Food Testing is a ~$2B Global Industry; Molecular, Contract Labs Gaining Share

We size the global food testing market at $2B, comprised of tests for pathogens, indicator organisms (e.g., organisms that are not inherently pathogenic, such as coliforms, yeast and molds), and chemical contaminants (e.g., allergens, mycotoxins and drug residues). The following table illustrates the respective sizing of these different market segments.

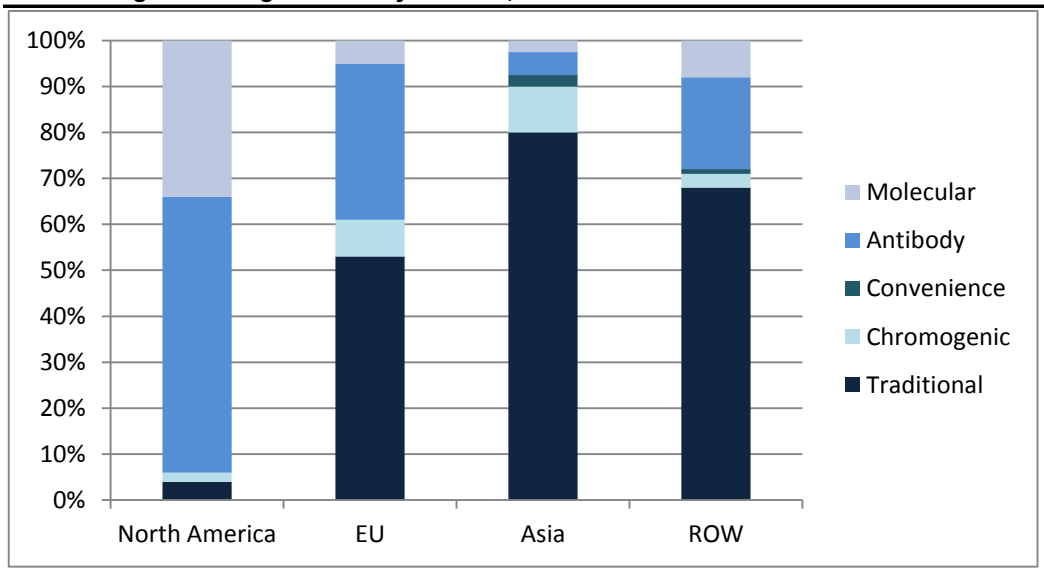
Global Food Testing Market Size ($M)



Source: Capella Advisors, ROKA, Leerink estimates.

The mix of molecular (i.e., PCR) vs. other methods used in pathogen testing varies by geography. We believe the U.S. is the heaviest adopter of molecular methods for food pathogen testing, with 35% - 40% of market volume counted as molecular. The rest of the world lags in molecular adoption. The following table illustrates a distribution of test method by geography.

% of Pathogen Testing Volume by Method, 2013

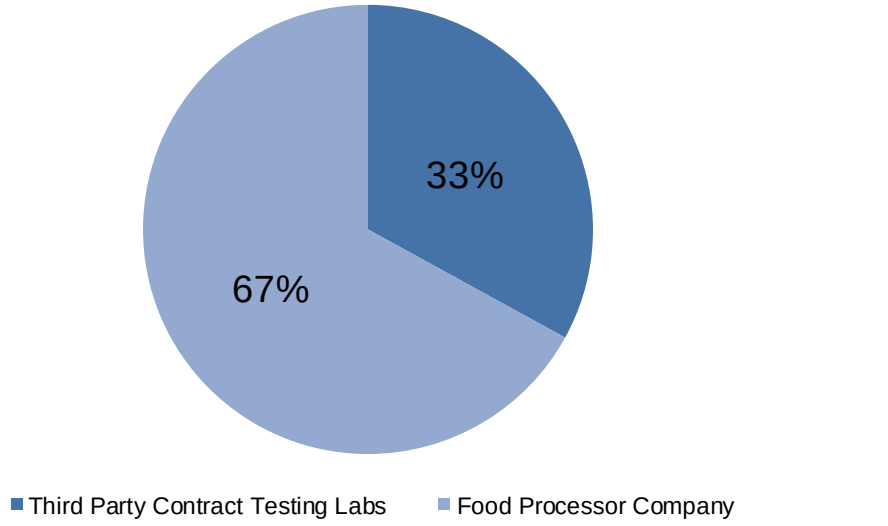


Source: Strategic Consulting Inc.

While molecular remains underpenetrated vs. its potential worldwide, we believe the category will grow faster than the overall pathogen testing market, a view that is supported by conversations with several industry sources.

Additionally, due to ever increasing testing complexity and regulatory requirements, third-party contract labs are performing a greater proportion of total food test volume. We believe these labs now perform ~1/3 of pathogen tests in North America, and we expect this proportion will grow over the next several years.

% of Testing Volume by Location, 2013



Source: Capella Advisors, ROKA, Leerink estimates.

We consider this increase in market concentration a positive for ROKA, since automation, throughput, and matrix versatility are features relatively more important for contract testing labs than for food processing labs.

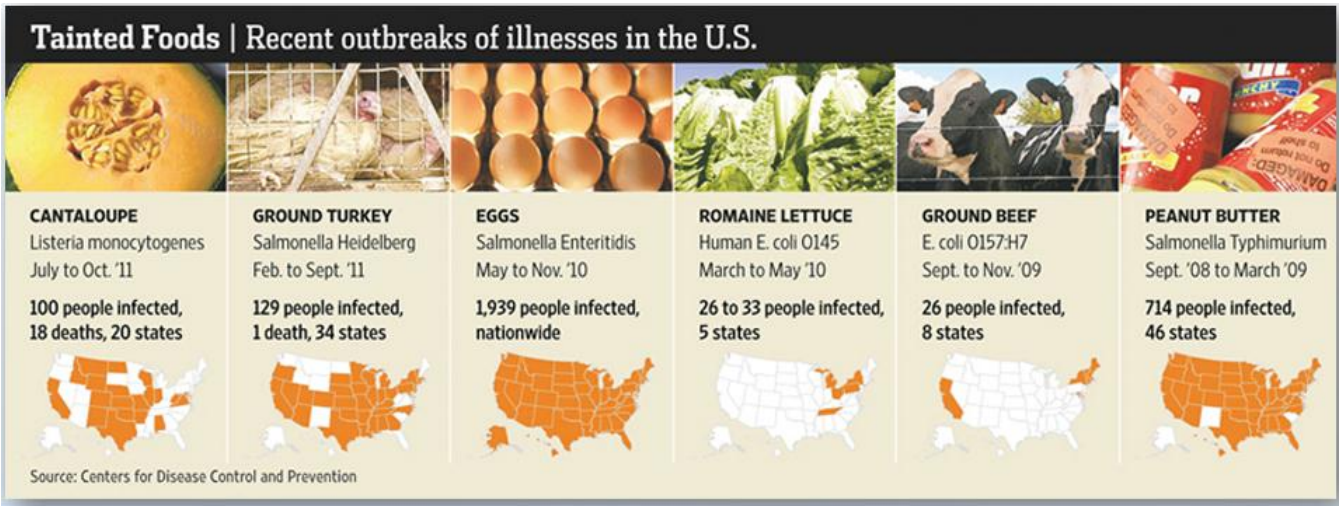
INDUSTRY BACKDROP

Increased Globalization, Proliferation of Recalls, and Regulation Drive Demand

Increased globalization and industrialization. The increased globalization and industrialization of the food supply is driving demand for increased testing for a number of foods. The U.S. imports approximately 15% of its food supply, including an increasing supply from developing countries that have less rigorous or lack food safety standards and processes. We expect the proportion of imported food will grow, a trend that will likely lead to an increase in the number of FDA Regional and/or District field labs. Furthermore, the increase in centrally processed and widely distributed foods will magnify the impact of a single contamination event.

Public health implications of food incidents and cost of outbreaks. The increasing number and magnitude of food recalls and consumer demand for safe food are also secular drivers of food testing. The CDC estimates 128k hospitalizations and 3k deaths from foodborne disease in the U.S. each year. The FDA and USDA reported 916 food recalls in the first nine months of 2013. According to a 2013 Grocery Manufacturers Association (GMA) survey of its membership, 58% of respondents were affected by a recall in prior 5 years, and 52% experienced recalls with a financial impact > $10 million. The cost of foodborne outbreaks can be terribly expensive and even

result in criminal liability as exhibited in the following cases: peanut butter (salmonella) = $1B+, spinach (e coli) = $25M - $50M, pet food (melamine) = $40M+; Jensen brothers (salmonella/cantaloupe) found criminally liable. The following table illustrates some of these high profile outbreaks.



Regulatory or legislative mandates. Both regulatory changes by the FDA and/or the USDA and legislative changes by Congress have driven changes in food testing methods or spurred adoption of a new technology/method in the food testing market. We expect the Food Safety Modernization Act (FSMA) will drive an increase in pathogen testing. Recall, FSMA (signed into law in 2011) was designed to improve the capacity to prevent, detect, and respond to food safety problems, and to improve the safety of imported food. The FDA is still in the process of writing new and proposed FSMA rules, which will be phased-in; the largest industry participants will be the first subject to the new regulations. ROKA is well-positioned to capitalize on FSMA mandates as it has penetrated large contract testing labs and food processors in North America. Since many of the proposed rules are not final, neither the economic impact nor the incremental magnitude for testing has been quantified; however, a regulator with whom we spoke indicated that the regulations would increase the demand for new food testing industry-wide.

Examples of other precedent regulatory and legislative mandates that influenced food testing include:

- The Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) final rule
- The Food Quality Protection Act of 1996
- The Poultry Products Inspection Act of 1957
- The Federal Food, Drug, and Cosmetic Act (FFDCA)
- The Federal Meat Inspection Act (FMIA)
- The New Poultry Inspection System (NPIS)

The New Poultry Inspection System was announced on 7/31/2014. This rule requires that, for the first time ever, all poultry facilities will be required to perform their own microbiological testing at two points in their production process to show that they are controlling Salmonella and Campylobacter.

Rules and regulations such as these are certainly incremental positives for ROKA. These rules and regulations though will likely only establish the baseline of testing that food producers perform. We imagine that many will go over and above regulatory requirements in an effort to protect consumers, brands, and market share.

COMPETITIVE LANDSCAPE

Many Competitors, Few Focused

We count many companies among ROKA's competitive set in molecular food pathogen testing, but don't consider any or many to be as focused on food testing as ROKA. ROKA's largest direct competitor in molecular food pathogen testing is DuPont. However, DuPont's molecular testing system, the BAX Q7, was introduced in 2005 and is viewed in the market as stale, per our diligence. We thus believe DuPont is ripe to be a donor of market share. Newer molecular instruments from 3M (Molecular Detection System) and Neogen (ANSR) appear to us to be well suited for lower throughput, manual segments of the market. BIO (MP) is a contender in the molecular pathogen testing arena, and has front-end automation to compete in higher volume segments. QGEN (MP) markets its mericon assays and QIAsymphony instrument to food microbiology customers. TMO (OP) sells a couple of products into this market, both its SureTect PCR system, and PCR systems from Life Technologies. Invisible Sentinel uses the former for its Veriflow assays. The GDS instrument from BioControl has a following in molecular. Finally, Sample6 is an emerging player in the molecular arena, though its pathogen testing menu is currently more limited and its focus on environmental applications for the time being.

BioMerieux is by far the market leader in immunochemical testing for food pathogens; its VIDAS instrument is well recognized in the industry. However, the company's interest in entering molecular has been unclear. At a recent food industry meeting, the company highlighted potential applications for its recently acquired BioFire technology in the molecular arena.

Finally, homebrew molecular testing solutions crafted by contract testing labs must be considered as a competitor to ROKA. We believe one contract testing lab, IEH, has been using its own homebrew molecular pathogen tests for some time, but we do not necessarily see this phenomenon becoming a broader trend.

All of these testing methods force tradeoffs between accuracy, cost, time to results, and complexity/labor intensity of workflow.

VALUATION

Rapid Revenue Growth Justifies Premium Multiple

ROKA's current stock price implies an enterprise value that is ~14x our forward twelve month revenue forecast. This multiple is a premium to the median multiple for our broader life science tools and diagnostics coverage (~4x), and to the median of our emerging growth tools and diagnostics comp group (~5x), as illustrated in the following table. We included two more mature companies, bioMerieux and Neogen, into our valuation grid due to market overlap.

Emerging Growth Tools/Diagnostics Multiples

		Current price		Revenue (M$)		'14/ 15	Mkt cap / rev	
Company	Ticker	8/07/2014	Mkt Cap (M$)	2014e	2015e	Growth	2014e	2015e
Accelerate	AXDX	$17.00	$758	nm	nm	nm	nm	nm
BG Medicine	BGMD	0.88	$30	$6	$13	125%	5.3x	2.4x
bioMerieux (EUR)	BIM-FR	77.60	$3,061	$1,677	$1,779	6%	1.8x	1.7x
Combimatrix	CBMX	2.01	$22	$8	$12	51%	2.7x	1.8x
Cerus	CERS	3.74	$271	$38	$54	41%	7.1x	5.0x
Cancer Genetics	CGIX	10.10	$94	$15	$38	156%	6.2x	2.4x
Diadexus	DDXS	0.70	$38	$29	$33	13%	1.3x	1.2x
Exact Sciences	EXAS	16.04	$1,328	$2	$74	3473%	638.7x	17.9x
Fluidigm	FLDM	26.28	$737	$116	$148	28%	6.4x	5.0x
Foundation Medicine	FMI	23.63	$666	$58	$109	87%	11.5x	6.1x
GenMark	GNMK	11.12	$463	$25	$38	48%	18.2x	12.3x
Cellular Dynamics	ICEL	12.25	$193	$19	$41	115%	10.2x	4.7x
Liposcience	LPDX	2.99	$46	$39	$39	(0%)	1.2x	1.2x
Nanosphere	NSPH	0.95	$73	$15	$26	79%	5.0x	2.8x
Nanostring	NSTG	11.45	$207	$48	$72	52%	4.3x	2.9x
Neogen	NEOG	43.57	$1,600	$284	$322	13%	5.6x	5.0x
Oxford Immunotec	OXFD	13.25	$233	$49	$67	36%	4.7x	3.5x
PacBio	PACB	4.74	$334	$47	$63	33%	7.1x	5.3x
Sequenom	SQNM	3.81	$443	$169	$219	30%	2.6x	2.0x
Trovagene	TROV	3.15	$60	$0	$5	1752%	225.5x	12.2x
Veracyte	VCYT	14.51	$307	$40	$77	90%	7.6x	4.0x
Vermillion	VRML	2.02	$72	nm	nm	nm	nm	nm
Intrexon	XON	$22.54	$2,228	$48	$80	67%	46.8x	28.0x
MEDIAN (OVERALL)						51%	6.2x	4.0x

Source: Leerink Partners, FactSet (all estimates are FactSet consensus)

We believe it reasonable that ROKA be awarded a premium revenue multiple for many reasons. The company is very early in its technology adoption curve, boasts a unique asset in a growth industry, and is not subject to any of the external uncertainties which impact many of the companies in this peer group, namely uncertainties over FDA regulation and reimbursement. That said, we believe it reasonable to assume that ROKA's valuation multiple compresses over time. Our 12-month price target of $13 represents an enterprise value, using projected levels of debt and cash that is ~7.5x our revenue forecast for the twelve months ended June 2016.

RISKS TO VALUATION

The primary risks to our price target for ROKA include, but are not limited to: the trajectory of the company's revenue ramp, ability to attract new customers and covert traditional testing methods to molecular, competitive pressures from incumbent and emerging food testing technologies, and failure to innovate product lines.

MANAGEMENT

Paul G. Thomas, CEO. Mr. Thomas joined ROKA Bioscience as CEO and Founder in September 2009. Mr. Thomas previously served as Chairman, Chief Executive Officer and President of LifeCell Corporation, a publicly traded regenerative medicine company, from 1998 until it was acquired by KCI in 2008. Prior to joining LifeCell, Mr. Thomas held various senior positions during his tenure of 15 years with Ohmeda, a world leader in inhalation anesthetics and acute care pharmaceuticals. Mr. Thomas received his M.B.A. degree from Columbia University Graduate School of Business and completed his postgraduate studies in Chemistry at the University of Georgia Graduate School of Arts and Science. He received his B.S. degree in Chemistry from St. Michael's College in Vermont.

Steven T. Sobieski, SVP/CFO. Mr. Sobieski joined ROKA Bioscience in September 2009. Prior to joining ROKA, Mr. Sobieski served from 2000 to 2009 as senior vice president and chief financial officer at LifeCell Corporation. Mr. Sobieski was vice president of finance at Osteotech, Inc., a public company focused on orthopedic products, where he also served in other positions, from 1991 to 2000. From 1981 through 1991, Mr. Sobieski was with Coopers & Lybrand, a public accounting firm. Mr. Sobieski received his BS in business administration from Monmouth University, his MBA degree with a concentration in accounting from Rutgers University, and he is a CPA.

A.J. McCardell, SVP, Commercial Operations. Ms. McCardell joined ROKA Bioscience in May 2010. Before joining ROKA's Executive Team, Ms. McCardell was with Lonza Bioscience, serving as Global Director of Commercial Development for their Rapid Testing business from 2005 to 2010, and as the Business Unit Director of food safety testing for Strategic Diagnostics from 2001 to 2005. From 1992 to 2001, Ms. McCardell held positions of increasing responsibility at Dupont-Qualicon, where she assisted in the development, launch, and sale of the DuPont Riboprinter and BAX Systems, which became the market leader in molecular-based pathogen detection and identification systems for the food industry. Ms. McCardell received an M.S. degree in Soil Microbiology from the University of Delaware and conducted post-graduate studies in molecular microbiology at the University of Minnesota. She received her B.S. in Biology from Lebanon Valley College in Pennsylvania.

Wally Narajowski, SVP, General Manager. Mr. Narajowski joined ROKA Bioscience as SVP and General Manager of the San Diego operation. Before joining ROKA, Mr. Narajowski served from 2005 to 2008 as president, chief executive officer of Pathway Diagnostics, a biomarker development and testing company, which was sold to Quest Diagnostics. Prior to Pathway, Mr.

Narajowski served as vice president, general manager of Focus Diagnostics, an infectious disease reference laboratory and diagnostic product business. The majority of Mr. Narajowski's career was with Abbott Laboratories where he served as vice president, general manager of critical care products, vice president, general manager of the infusion pump business, general manager of physician office diagnostics, and a director of research and development. Mr. Narajowski received his MS in bioengineering from the University of Utah, and his BS in electrical engineering from the Illinois Institute of Technology.

Michael Becker, VP of Research and Development. Dr. Becker joined ROKA Bioscience as Vice President of Assay Research and Development in September 2009. Before joining ROKA, Mick worked 16 years at Gen-Probe, Inc. (now Hologic) in the Research Department. Mick has published over 100 papers and patents including over 40 issued US patents. Before joining Gen-Probe Mick was an Associate Professor in the Institute of Biosciences and Technology at Texas A&M University, an Assistant Professor in the Department of Biological Sciences at the University of Pittsburgh and an Anna Fuller Postdoctoral Fellow at Harvard with James C. Wang. Mick received his Ph.D. in Chemistry from Caltech in 1981 under Peter B. Dervan.

David R. Patterson, VP of Manufacturing Operations. Mr. Patterson joined ROKA Bioscience as Vice President of Operations in September 2009. Prior to joining ROKA Bioscience, Mr. Patterson served as the Associate Director of Process Transfer at Gen-Probe, Inc. (now Hologic). Mr. Patterson's 10-year tenure at Gen-Probe also included the following positions: Scientist on the HIV-1/HCV assay development team, Manager of the Process Support group, and Manager of Process Transfer. In addition, Mr. Patterson held various roles over 8 years at Ortho-Clinical Diagnostics, a subsidiary of Johnson & Johnson. He began as a research scientist where he earned patents in real-time PCR, carryover prevention methodology, and detection of HIV-1/HCV. He completed his career at Ortho-Clinical as the Operation's Supervisor of the FDA (CBER) approved manufacturing facility for blood screening tests. Mr. Patterson received his B.S. degree in Biochemistry from the University of California at Riverside.

Lars Boesgaard, VP of Finance. Mr. Boesgaard joined Roka Bioscience in October 2009. Before joining Roka, Mr. Boesgaard was Vice President of Finance at Insulet Corporation from 2007 to 2009. From 2004 to 2007, Mr. Boesgaard served as Sr. Director of Financial Services for Alexion Pharmaceuticals, Inc. Mr. Boesgaard began his career holding various finance positions at Novo Nordisk A/S in Denmark and Japan. Mr. Boesgaard earned a BS in business administration from Copenhagen Business School and an MBA from the Richard Ivey School of Business at Western University in Ontario, Canada.

Roka Biosciences (ROKA)

Income Statement

Dan Leonard, 212-277-6116
dan.leonard@leerink.com

Period Ended *($ thousands)*	2012	2013	Mar-14	Jun-14e	Sep-14e	Dec-14e	2014e	2015e	2016e	2017e	2018e
Revenue											
Product	**$105**	**$2,182**	**$828**	**$1,360**	**$2,125**	**$3,825**	**$8,138**	**$24,429**	**$45,194**	**$66,195**	**$92,514**
Other	0	0	0	0	0	0	0	0	0	0	0
Total revenue	105	2,182	828	1,360	2,125	3,825	8,138	24,429	45,194	66,195	92,514
COGS	3,186	6,600	1,265	2,271	2,486	2,945	8,968	17,589	25,760	33,098	41,631
Gross profit	(3,081)	(4,418)	(437)	(911)	(361)	880	(830)	6,840	19,433	33,098	50,883
SG&A	16,052	17,651	5,090	5,617	5,695	6,082	22,484	23,208	26,212	28,464	30,530
R&D	9,584	7,568	1,842	2,285	2,231	2,372	8,730	7,329	8,135	8,605	9,251
Operating income (loss)	**(28,717)**	**(29,637)**	**(7,369)**	**(8,813)**	**(8,288)**	**(7,574)**	**(32,043)**	**(23,696)**	**(14,914)**	**(3,972)**	**11,102**
Interest expense (income)	140	3,033	389	403	395	387	1,575	1,571	1,608	1,631	1,630
Other expense, net	(4,996)	0	0	0	0	0	0	0	0	0	0
Pretax income	(23,861)	(32,670)	(7,758)	(9,216)	(8,683)	(7,961)	(33,618)	(25,268)	(16,522)	(5,602)	9,472
Taxes	(763)	0	6	0	0	0	6	0	0	0	3,315
Net income	($23,098)	($32,670)	($7,764)	($9,216)	($8,683)	($7,961)	($33,624)	($25,268)	($16,522)	($5,602)	$6,157
Basic shares outstanding		9,069	11,106	12,632	16,862	17,632	14,558	17,757	17,957	18,157	18,357
Diluted shares outstanding		9,069	11,106	12,632	16,862	17,632	14,558	17,757	17,957	18,157	19,357
EPS diluted		**($3.60)**	**($0.70)**	**($0.73)**	**($0.51)**	**($0.45)**	**($2.40)**	**($1.42)**	**($0.92)**	**($0.31)**	**$0.32**
EPS growth											
Sales growth		1978.1%	211.2%	102.8%	281.8%	455.2%	273.0%	200.2%	85.0%	46.5%	39.8%
Gross margin	(2934.3%)	(202.5%)	(52.8%)	(67.0%)	(17.0%)	23.0%	(10.2%)	28.0%	43.0%	50.0%	55.0%
SG&A % of revenue	15287.6%	808.9%	614.7%	413.0%	268.0%	159.0%	276.3%	95.0%	58.0%	43.0%	33.0%
R&D % of revenue	9127.6%	346.8%	222.5%	168.0%	105.0%	62.0%	107.3%	30.0%	18.0%	13.0%	10.0%
Operating margin	**(27349.5%)**	**(1358.2%)**	**(890.0%)**	**(648.0%)**	**(390.0%)**	**(198.0%)**	**(393.7%)**	**(97.0%)**	**(33.0%)**	**(6.0%)**	**12.0%**
Tax rate	3.2%	0.0%	(0.1%)	0.0%	0.0%	0.0%	(0.0%)	0.0%	0.0%	0.0%	35.0%
D&A	$2,045	$2,437	$661	$1,175	$1,190	$1,206	$4,232	$8,593	$6,876	$7,150	$7,570
EBITDA	**($26,672)**	**($27,200)**	**($6,708)**	**($7,637)**	**($7,098)**	**($6,367)**	**($27,810)**	**($15,103)**	**($8,038)**	**$3,178**	**$18,672**
Free cash flow											
Operarating cash flow	($27,774)	($27,452)	($4,181)				($23,438)	($15,388)	($7,947)	$4,205	$17,524
CapX	(5,929)	(3,410)	12				(3,483)	(4,701)	(6,578)	(7,919)	(9,277)
Free cash flow	($33,703)	($30,862)	($4,169)				($26,922)	($20,089)	($14,525)	($3,714)	$8,248

Notes:

Source: Company reports and Leerink Partners estimates

Balance Sheet *($ thousands)*	Sep-13	Dec-13	Mar-14	Jun-14e	Sep-14e	Dec-14e
Assets						
Cash, equivalents, and short-term investments	$17,964	$32,728	$32,699	$25,932	$65,698	$57,746
Accounts receivable	241	277	515	522	815	1,467
Inventory	3,786	3,879	4,180	3,236	3,542	4,196
Other	1,218	5,572	3,031	544	850	1,530
Total current assets	23,209	42,456	40,425	30,233	70,905	64,939
Property and equipment, net	15,115	14,510	13,860	13,432	13,600	13,784
Goodwill	360	360	360	360	360	360
Other intangibles	1,386	1,344	1,302	1,302	1,302	1,302
Other	264	444	333	333	333	333
Total assets	$40,334	$59,114	$56,280	$45,660	$86,500	$80,718
Liabilities and shareholders' equity						
Notes payable and current maturities of long-term de	$0	$4,919	$9,725	$1,459	$1,459	$1,459
Accounts payable	941	1,226	433	872	1,836	2,367
Accruals and other	1,760	2,720	3,094	1,197	1,870	3,366
Total current liabilities	2,701	8,865	13,252	3,528	5,165	7,191
Long-term debt	0	0	0	8,266	8,266	8,266
Deferred payments	3,196	3,205	3,212	0	0	0
Other	528	591	1,566	1,566	1,566	1,566
Total liabilities	$6,425	$12,661	$18,030	$13,360	$14,997	$17,024
Convertible preferred stock	$124,030	$127,797	$127,700	$127,700	$0	$0
Shareholders' equity	($90,121)	($81,344)	($89,450)	($98,612)	$71,502	$63,695
Total liabilities, shareholders' equity, and minority inter	$40,334	$59,114	$56,280	$42,448	$86,500	$80,718

Disclosures Appendix

Analyst Certification

I, Dan Leonard, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Distribution of Ratings/Investment Banking Services (IB) as of 06/30/14			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	138	69.00	50	36.20
HOLD [MP]	62	31.00	2	3.20
SELL [UP]	0	0.00	0	0.00

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform in line with its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark over the next 12 months.The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over $2 billion.

Important Disclosures

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Leerink Partners LLC Equity Research

Director of Equity Research	**John L. Sullivan, CFA**	(617) 918-4875	john.sullivan@leerink.com
Associate Director of Research	**Alice C. Avanian, CFA**	(617) 918-4544	alice.avanian@leerink.com
Healthcare Strategy	**John L. Sullivan, CFA**	(617) 918-4875	john.sullivan@leerink.com
	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com
Biotechnology	**Howard Liang, Ph.D.**	(617) 918-4857	howard.liang@leerink.com
	Joseph P. Schwartz	(617) 918-4575	joseph.schwartz@leerink.com
	Michael Schmidt, Ph.D.	(617) 918-4588	michael.schmidt@leerink.com
	Gena Wang, Ph.D., CFA	(212) 277-6073	gena.wang@leerink.com
	Jonathan Chang, Ph.D.	(617) 918-4015	jonathan.chang@leerink.com
	Paul Matteis	(617) 918-4585	paul.matteis@leerink.com
	Richard Goss	(617) 918-4059	richard.goss@leerink.com
Life Science Tools	**Dan Leonard**	(212) 277-6116	dan.leonard@leerink.com
and Diagnostics	Justin Bowers, CFA	(212) 277-6066	justin.bowers@leerink.com
Pharmaceuticals/Major	**Seamus Fernandez**	(617) 918-4011	seamus.fernandez@leerink.com
	Ario Arabi	(617) 918-4568	ario.arabi@leerink.com
	Aneesh Kapur	(617) 918-4576	aneesh.kapur@leerink.com
Specialty Pharmaceuticals	**Jason M. Gerberry, JD**	(617) 918-4549	jason.gerberry@leerink.com
Medical Devices, Cardiology	**Danielle Antalffy**	(212) 277-6044	danielle.antalffy@leerink.com
	Puneet Souda	(212) 277-6091	puneet.souda@leerink.com
& Orthopedics	**Richard Newitter**	(212) 277-6088	richard.newitter@leerink.com
	Ravi Misra	(212) 277-6049	ravi.misra@leerink.com
Healthcare Services	**Ana Gupte, Ph.D.**	(212) 277-6040	ana.gupte@leerink.com
Healthcare Technology	**David Larsen, CFA**	(617) 918-4502	david.larsen@leerink.com
& Distribution	Christopher Abbott	(617) 918-4010	chris.abbott@leerink.com
Sr. Editor/Supervisory Analyst	**Mary Ellen Eagan, CFA**	(617) 918-4837	maryellen.eagan@leerink.com
Supervisory Analysts	Robert Egan		bob.egan@leerink.com
	Amy N. Sonne		amy.sonne@leerink.com
Editorial	Cristina Diaz-Dickson	(617) 918-4548	cristina.diaz-dickson@leerink.com
Research Assistant	Carmen Augustine	(212) 277-6012	carmen.augustine@leerink.com

New York
299 Park Avenue, 21st floor
New York, NY 10171
(888) 778-1653

Boston
One Federal Street, 37th Floor
Boston, MA 02110
(800) 808-7525

San Francisco
201 Spear Street, 16th Floor
San Francisco, CA 94105
(800) 778-1164