

# OHSU Board of Directors Meeting

September 18, 2014 1:30 pm – 3:30 pm

Malinow Hall, Oregon National Primate Research Center, W. Campus

# OREGON HEALTH & SCIENCE UNIVERSITY BOARD OF DIRECTORS MEETING

#### September 18, 2014 1:30 – 3:30 p.m. Oregon National Primate Research Center Administration Building

1:30 p.m.	Call to Order/ Chairman's Comments President's Comments Approval of Minutes (Action)	Jay Waldron Joe Robertson, M.D. Jay Waldron
1:45 p.m.	Welcome and Overview: Oregon National Primate Research Center	Nancy Haigwood, Ph.D.
2:05 p.m.	Preliminary FY14 Financial Results	Lawrence Furnstahl
2:20 p.m.	Ending AIDS at OHSU	Louis Picker, M.D.
2:35 p.m.	The Radiochemistry Research Center: Vision and Opportunities	William Rooney, Ph.D.
2:50 p.m.	OHSUF Update	Keith Todd



# Oregon Health & Science University Board of Directors Meeting June 26, 2014

Following due notice to the public, the regular meeting of the Board of Directors of Oregon Health & Science University (OHSU) was held at 1:30 pm in the School of Nursing, Room 358/364, located at 3455 SW Veterans Hospital Road, Portland, Oregon.

A transcript of the audio recording was made of these proceedings. The recording and transcript are both available by contacting the OHSU Board Secretary at 3181 SW Sam Jackson Park Road, Mail Code L101, Portland, Oregon 97239. The following written minutes constitute a summary of the proceedings.

#### **Attendance**

A quorum of the Board was present. Board members in attendance were Jay Waldron, Chair, presiding; Maria Pope, Vice Chair; Ken Allen; Frank Toda; Poorav Patel; Joe Robertson; MardiLyn Saathoff; Amy Tykeson; and David Yaden. Also present were Lawrence Furnstahl, Chief Financial Officer; Chuck Kilo, Chief Medical Officer; Jenny Mladenovic, Provost; Greg Moawad, Director, Public Safety; David Robinson, Executive Vice Provost; Connie Seeley, Board Secretary and OHSU Chief of Staff; other OHSU staff members and members of the public.

#### **Call to Order**

Jay Waldron called the meeting to order at 1:38 p.m. Mr. Waldron briefly outlined the meeting agenda and asked Joe Robertson to begin the meeting with the president's comments.

#### **President's Comments**

Dr. Robertson's comments covered the following topics:

#### Collaborative Life Sciences Building (CLSB) Opening

Dr. Robertson mentioned that this new building is an application of collaboration and innovation, made possible by the three institutions, government entities, and our philanthropic partners. It allows for increases in students in PA, dental, medical, and pharmacy programs.

#### **OHSU Graduations**

We now graduate over 1,000 students per year. There are over 3,000 students on campus at any given time.

#### **Research Programs**

Our research programs are still 14% ahead of last year in the awards that we've received notification for at a time of flat NIH funding.

#### Scholars for a Healthy Oregon

We now have our first and full contingent of scholars for this program. This program promises tuition for those that are willing to serve in an underserved area in Oregon.

#### **Arming OHSU Public Safety Officers**

On the agenda today is a resolution which would authorize OHSU police officers to carry firearms.

#### **Approval of Minutes**

Mr. Waldron asked for the approval of the minutes of the April 24, 2014 Board meeting, included in the Board Docket. Upon motion duly made by Ms. Pope and seconded by Ms. Saathoff, the minutes were unanimously approved.

#### **Financial Update**

Resolution 2014-06-05: Operating Budget, Capital Budget and Academic Year Fee Book

Lawrence Furnstahl presented financial results for the first 11 months of the current fiscal year, as well as the operating and capital budgets for the next fiscal year. He noted that expansion of health insurance coverage in Oregon has happened faster than expected. Other positive trends include grant awards, fundraising, output of science metrics, and the addition of new jobs. Budget highlights include enhanced support for faculty, the inclusion of CLSB operating costs in the budget, control overhead costs held to 2% growth, and the continuation of the OHSU Tuition Promise program. The Radiochemistry Research Center, a major science initiative that is under consideration, is included in the capital budget.

MardiLyn Saathoff asked if the Research Imaging Institute is just \$2 million in this budget. Mr. Furnstahl confirmed it is just \$2 million in this budget and that the whole program is \$32 million; this is just next year's piece, largely for design.

Dr. Jeanette Mladenovic commented on the tuition and fees, stating that increases in tuition, health insurance, and fees were lower than in prior years.

Poorav Patel inquired about the 7% tuition increase for the dental school vs. the 2% increase for the medical school. Mr. Furnstahl explained that this increase was arrived at after looking at different benchmarks such as other dental school's tuition rates, debt levels, and initial earning levels of graduates, to put together the package that afforded the new School of Dentistry at the South Waterfront.

Responding to Mr. Patel's question about the long-term cost of tuition management, Mr. Furnstahl explained that OHSU's new way of budgeting helps with understanding the true cost of academic activities, and will be further refined by differentiating education and research within the academic piece. Another part of tuition management is raising endowment for student aid. The third part of the

strategy is managing administrative costs. Dr. Mladenovic commented that OHSU has also put additional dollars into scholarship from operational dollars, and that the faculty in the CLSB will now be able to teach across schools and programs, instead of focusing in just one.

Mr. Patel inquired about health insurance for students. Since it is different from what is offered to employees, would it be possible to purchase insurance through the exchange? Dr. Mladenovic explained that she anticipates that insurance costs will go down due to a new insurance program for our students.

Amy Tykeson asked Lawrence Furnstahl about ease of comparing this fiscal year to last fiscal year, given that now there is a new way of budgeting with more transparency. Mr. Furnstahl responded that there will be a transition period where giving a detailed comparison of this year with a prior year will be more difficult, but there is no problem on the aggregate performance of OHSU.

Hearing no further questions or comments on the financial report, Mr. Waldron called for a motion on Resolution 2014-06-05, which approves and adopts the FY 14-15 Operating Budget, including the tuition and fees for the academic year 2014-15 as shown in the OHSU Academic Year Fee Book, and the FY14-15 Capital Budget. Upon motion duly made by Mr. Yaden and seconded by Ms. Pope, the resolution was unanimously approved.

#### **State Achievement Compact**

Resolution 2014-06-06: Achievement Compact with Oregon Education Investment Board

Mr. Waldron introduced David Robinson, Executive Vice-Provost, to present on State Achievement Compacts.

Dr. Robinson went into detail about the history of the State Achievement Compacts, the goals, and how OHSU is managing those goals.

Ms. Tykeson asked Dr. Robinson if the numbers increase from the KPIs from the State from 70% to 50% as we move forward. Dr. Robinson replied that they do not.

Mr. Yaden commented on two aspects of the Achievement Compacts. Until now, they have been mostly projections of what we already know rather than true achievement targets. In addition, until they are linked to funding mechanisms and budgets are set, it remains uncertain if they are just projections or true achievement compacts related to the budgets.

Ms. Saathoff inquired if the intent of the legislation was to set hard targets and attach dollars to those targets. Mr. Yaden explained that the targets would link to a new output-based funding mechanism for the state.

Resolution 2014-06-06 enters OHSU into the Achievement Compact with the Oregon Education Investment Board. Upon motion duly made by Dr. Toda and seconded by Ms. Saathoff, the resolution was unanimously approved.

#### **Commissioning of Firearms for University Police Officers**

Resolution 2014-06-07: Commissioning university police officers to carry firearms

Mr. Waldron introduced Greg Moawad, Director of Public Safety, to present on arming of OHSU public safety officers.

Mr. Moawad provided a recap of the process OHSU has undertaken over a period of years regarding the pros and cons of arming our officers. He highlighted the collaborative effort used to bring various factions together to weigh all sides of this issue.

Ms. Saathoff asked if the requirements to get into the training program that Mr. Moawad described are the same as for other government law enforcement officers. Mr. Moawad assured her that they are the same.

Ms. Tykeson asked if the OHSU officers are police officers first, with the additional training on top of that. Mr. Moawad indicated that that is correct.

Dr. Robertson thanked Mr. Moawad for his efforts on this front. He also said that this initiative was undertaken in the spirit of OHSU's mission statement, which is to improve the health and well-being of all Oregonians.

Ms. Tykeson asked Mr. Moawad if he is being sought out as a best practices entity now that this program has been developed. Mr. Moawad replied that he is.

Mr. Yaden commended Mr. Moawad on the attention he's given to training around mental health issues, and the situation this puts public safety officers in.

Mr. Allen remarked that it is important for OHSU to recruit the right kind of officer, and to get the word out that our officers are police officers; perhaps the department should be known as a police department instead of the Department of Public Safety.

Dr. Toda told Mr. Moawad that he himself has 30 years in security, disaster preparedness, and the military. He is very impressed with how Mr. Moawad handled the questions he posed to him offline.

Resolution 2014-06-07 authorizes the President or the President's designee to authorize commissioned university police officers to carry firearms at any time on and after September 15, 2014, subject to completion by such officers of appropriate training approved by the OHSU Director of Public Safety.

Upon motion duly made by Mr. Allen and seconded by Ms. Saathoff, the resolution was unanimously approved.

#### **OHSU Healthcare Quality and Safety Report**

Mr. Waldron then introduced Dr. Chick Kilo, Vice President and Chief Medical Officer, to present on the OHSU Healthcare Quality and Safety Report.

Dr. Kilo spoke of the ongoing effort in the clinical enterprise area on performance improvement targets, and what has been achieved over the last two years. He spoke of OPEx, the OHSU Performance Excellence Systems.

Mr. Waldron asked Dr. Kilo what OPEx means to a patient, and what effect can the Board have on OPEx. Dr. Kilo answered that he believes patients rate OHSU on how well they are treated, and it should be reflective of the safety, quality, service and affordability of the experience. As for what effect the Board can have on OPEx, Dr. Kilo answered that he would invite the Board's involvement so that they would be better sponsors of the program.

Mr. Yaden cautioned that if one really wants to get more involved, be prepared to learn a whole dictionary of acronyms.

Mr. Patel asked if NYU or Emory have particular programs that allow them to be successful in the UHC top performers rating. Dr. Kilo responded that most on that list have been working on it for six to eight years. He mentioned that folks from OHSU are visiting several of the schools on the list to better learn what they are doing.

Ms. Saathoff stated that Dr. Kilo had mentioned that OHSU is basically at the second stage, and that OHSU will start to see some results when it gets to the third stage--a stage where the system is in place, and there is more alignment. Dr. Kilo agreed.

Ms. Pope asked if Dr. Kilo could bring an example to the Board and walk them through it. Dr. Kilo said he would.

Mr. Yaden added that a more enlightening experience would be not just getting a briefing from Dr. Kilo, but actually attending one of the huddles they have with the people who are actually living this day by day.

Ms. Tykeson added that that is a cross-functional huddle, kind of this service profit chain, which leads to all kinds of good things. It's a cultural shift when you are on this continuum.

#### **Adjournment**

Hearing no further business, Mr. Waldron adjourned the meeting at 2:50 p.m.

Respectfully submitted,
Connie Seeley
Board Secretary





# **OHSU Board of Directors**

Oregon National Primate Research Center

Presented by: Nancy L. Haigwood, Ph.D. September 18, 2014

### **ONPRC** mission



To use scientific discovery, and, in particular, nonhuman primate (NHP) models, to accelerate progress in understanding human diseases, leading to better health

- ☐ Conduct state-of-the-art research for which nonhuman primates are uniquely suited for solutions of human health problems
- Provide a national resource to conduct interdisciplinary biomedical research, especially as it relates to nonhuman primates
- Pursue the highest standards of humane and responsible animal care
- Provide research training and experience for those preparing to enter research and biological teaching careers



### Value of NHP models is increasing



- NHP models provide a crucial link between preclinical and clinical studies (mechanisms, proof-of-concept)
- Similarities between NHP and human physiology and pathophysiology allow robust extrapolation to human disease
- Comprehensive analyses of systems, including noninvasive imaging, has enhanced the value of the models and increased interdisciplinary research
- Models for specific diseases are a reality and more are in development, particularly targeting neurological conditions and cancer

- Maintains over 4,700 pathogen-free rhesus monkeys; sub-population of Japanese macaques, baboons, cynomolgus macaques
  - Aging colony
  - o ID/AIDS research colony
  - Obese resource
  - o Fertile females
- 15 Veterinarians and > 130 animal care staff
  - Surgery, pathology, behavioral units
  - Primate genetics program
  - o MRI, other state-of-the-art imaging
- Contributes to the nationwide consortium of purpose-bred primates



# Strategic recruitment to catalyze interdisciplinary opportunities: 8 new early stage faculty

#### Pathobiology & Immunology: Scott Wong

- HIV/AIDS and other vaccines
- Multiple sclerosis infection model
- Cytomegalovirus models and vectors



Five interdisciplinary research groups

#### Reproductive & Developmental Science: Jon Hennebold

- Contraception
- Stem cell biology
- Oncofertility

#### Neuroscience: Kathy Grant

- Neurodegeneration
- Macular degeneration
- Addiction (alcohol, nicotine)

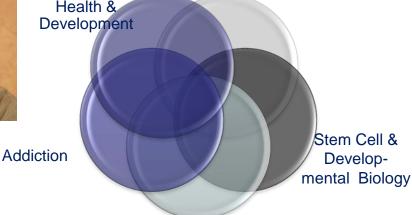


- Metabolic diseases
- Obesity-induced diabetes
- Cardiovascular disease







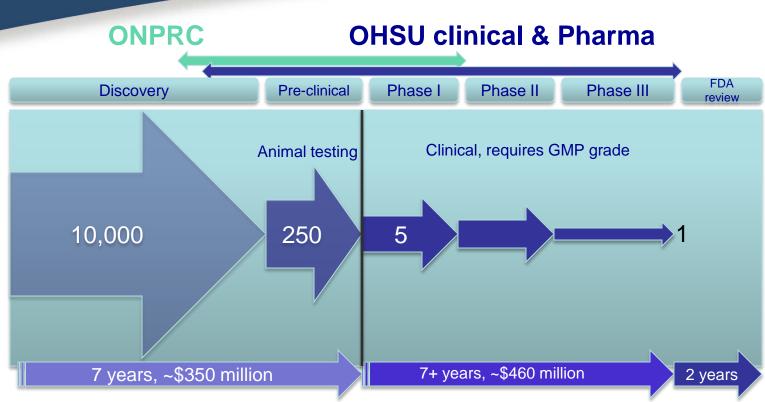


**Healthy Aging** 

Genetics



### Primate research accelerates product development: Go/No-Go decisions for drugs, vaccines, and therapies





OHSU CENTER FOR EMBRYONIC CELL AND GENE THERAPY Groundbreaking research in stem cell therapy Induced pluripotent cells Mitchondrial gene therapy Shoukhrat Mitalipovs, Ph.D. & Shawn Chavez, Ph.D.

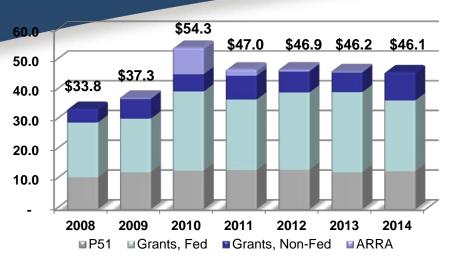
NOVO-NORDISK/OHSU/MONASH PARTNERSHIP Target discovery for therapeutics for obesity

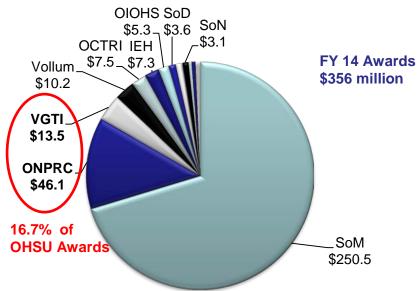




### Research funding for NHP research is growing







#### Trends in NIH funding for primate research

Fiscal Year	Total Projects	Total Funding	% change	% incr 08-13
2008	1,010	\$ 383.2		
2009	1,135	\$ 464.9	21.3%	
2010	1,086	\$ 496.2	6.7%	
2011	981	\$ 433.8	-12.6%	
2012	1,032	\$ 586.2	35.1%	
2013	997	\$ 572.1	-2.4%	49%

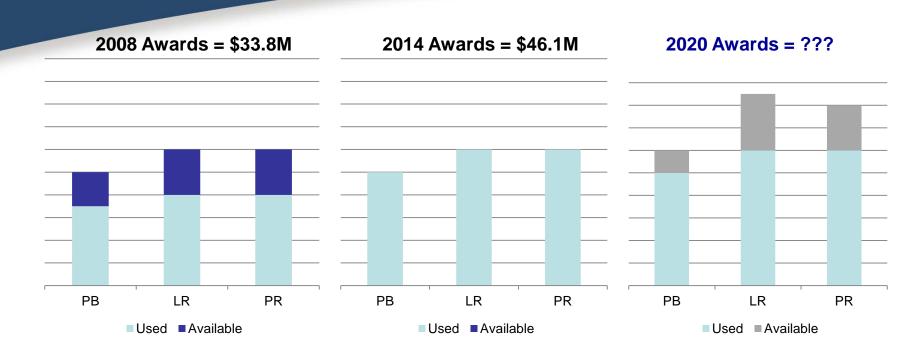
#### **Top Primate Research by Institution**

#### **Cumulative 2008-2013**

Emory	152.8
OHSU	150.9
Pittsburgh	91.9
Washington	74.1
Duke	70.6
Wake Forest	70.2
Mass Gen Hosp	68.4
Baylor	66.9
Johns Hopkins	64.7
Wisconsin, Madison	62.3
UC, Davis	60.1 OREGON
	HEAITH

Source: NIH Reporter, Excludes P51 Core grants

### Infrastructure investment will benefit OHSU



- Had available capacity to grow +30% since 2008
- Currently at capacity and holding at \$46M since 2012
- 2020 award growth target and infrastructure needs are in process via ongoing Strategic Planning

30% growth = \$59.8M 15% growth = \$52.9M 10% growth = \$50.6M

PB= Primate Breeding Space LR = Lab Research Space PR = Primate Research Space





# **FY14 Preliminary Financial Results**

OHSU Board of Directors September 18, 2014

### **FY14 Preliminary Financial Results**

- Preliminary FY14 OHSU operating income is \$90 million or 4% on \$2.3 billion of revenue, \$25 million over target on stronger than budgeted patient care payment rates across managed care, Medicaid and Medicare.
- Payer mix shows a marked decrease in uninsured activity since January, shifting to Medicaid with coverage expansion under the Affordable Care Act.
- New grant awards—a leading indicator of future revenues—ended FY14 up nearly 5% despite flat federal funding for NIH.
- There is a possible upward adjustment to net patient revenue pending that we should resolve in the next week.
- KMPG will update the Finance & Audit Committee on their year-end audit work at the October 10<sup>th</sup> meeting, and present their report to the full Board on October 23<sup>rd</sup>.



# **FY14 Results (continued)**

- Consolidated net worth is up \$201 million or 9%, from operating earnings, investment returns and major gifts, offset in part by writing off unamortized issuance costs from past bond issues, required by new GASB accounting rules.
- Through December, OHSU cash & investments were down \$(33) million, a decline that has now been reversed, reflecting \$37 million of positive cash flow in January – June, despite a significant slowdown in collections from a change in billing vendors.
- Reducing patient A/R and increasing cash is a prime focus for the first half of FY15.
- In addition, we implemented an accounting presentation change, moving the \$17 million of outstanding checks at June 30<sup>th</sup> from a liability to a deduction from cash balances, to reflect current best practice.



# **Unaudited FY14 Earnings \$25M > Budget**

June YTD (12 months) (millions)	FY13 Actual	FY14 Budget	FY14 Prelim	Prelim - Budget	Prelim / Last Year
Net patient revenue	\$1,520	\$1,606	\$1,640	\$34	8%
Grants & contracts	366	354	371	16	1%
Gifts applied to operations	65	72	67	(5)	3%
Tuition & fees	59	63	63	0	7%
State appropriations	30	32	35	3	17%
Other revenue	92	96	96	1	5%
Operating revenues	2,132	2,223	2,273	49	7%
Salaries & benefits	1,247	1,326	1,343	18	8%
Services & supplies	592	627	633	5	7%
Medicaid provider tax	54	67	69	1	27%
Depreciation	112	113	115	2	3%
Interest	29	25	23	(2)	-20%
Operating expenses	2,034	2,158	2,183	24	7%
Operating income	\$99	\$65	\$90	\$25	-9%

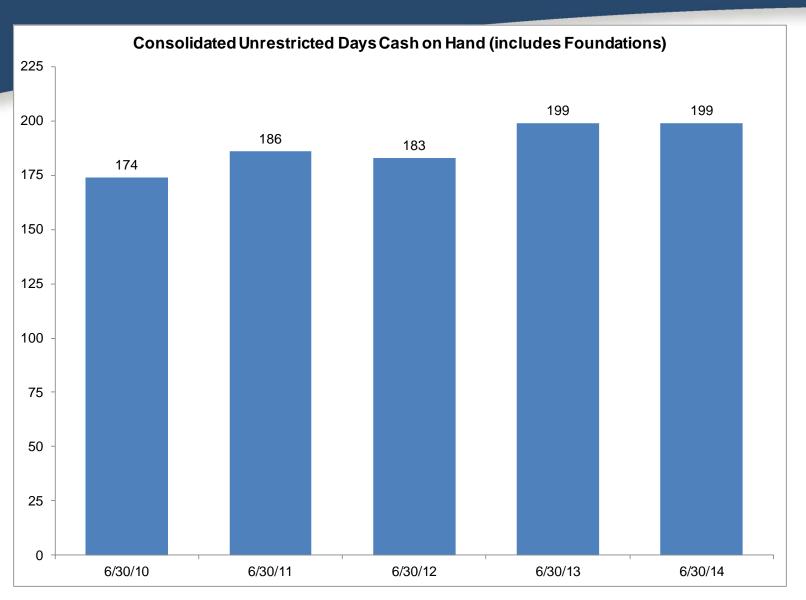


# A/R & Presentation Change Affect FY14 Cash

(millions)	6/30/13	6/30/14	Change	(millions)	June YTD
Operating cash & investments	\$592	\$587	<u>\$(5)</u>	Operating income	\$90
Outstanding check reclass	17	0	(17)	Depreciation	115
Quasi-endowment funds	83	92	10	OHSU investment return Capital gifts applied	34 27
OHSU cash & investments	692	679	(13)	CLSB project funds applied	34
Trustee-held bond funds	28	29	1	Soucres of cash	301
CLSB project funds	51	17	(34)		
				Principal repaid	(13)
Total cash & investments	771	725	(46)	Capital spending	(219)
				Patient accounts receivable	(49)
Net physical plant	1,413	1,517	103	Outstanding check reclass	(17)
Interest in Foundations	765	829	64	Working captial & other, net	(16)
Long-term debt	(771)	(758)	13		
Working capital & other, net	(8)	59	68	Uses of cash	(314)
OHSU net worth	2,170	2,371	201	Sources less uses of cash	(13)
	Operating inc	ome	90	6/30/13 balance	692
	OHSU investr	ment return	34	6/30/14 balance	\$679
Gain from Foundations		64			
	Capital gifts applied		27		
	Other non-ope	erating	(13)		
	Total change	in net worth	<u>\$201</u>		



# Days Cash on Hand Flat with Gift Funds

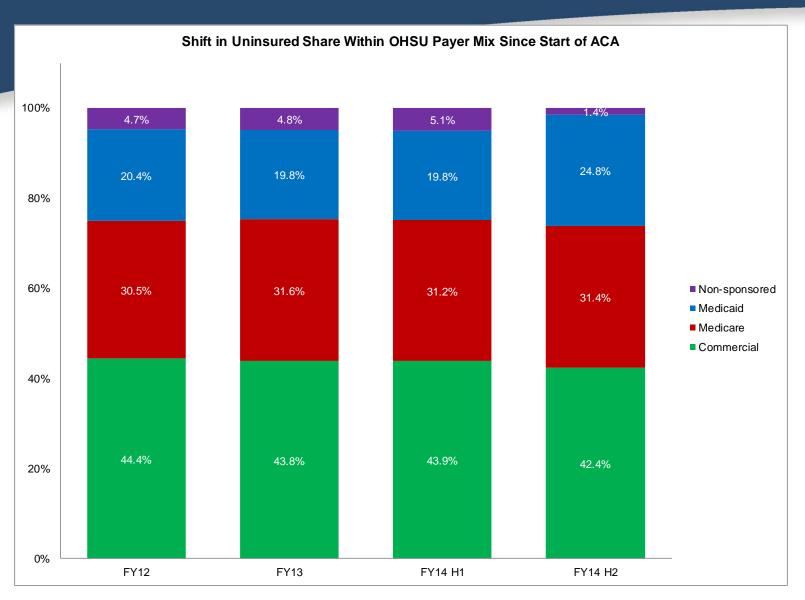


# Activity Shifts to Outpatient with Strong Mix

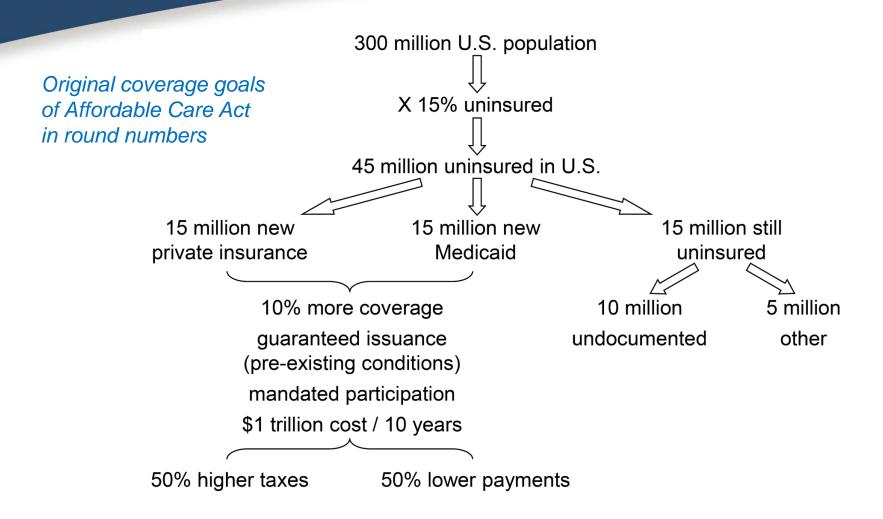
	June YTD (12 months)	FY13 Actual	FY14 Budget	FY14 Actual	Actual / Budget	Actual / Last Year
	Inpatient admissions	29,748	30,824	28,535	-7%	-4%
	Average length of stay	5.6	5.5	5.8	5%	3%
	Average daily census	446	455	442	-3%	-1%
$\rightarrow$	Day/observation patients	31,752	32,777	34,096	4%	7%
	Emergency visits	46,991	46,067	45,611	-1%	-3%
	Ambulatory visits	766,912	811,703	766,918	-6%	0%
	Surgical cases	30,450	31,279	30,414	-3%	0%
	Casemix index	1.97	1.96	1.97	1%	0%
	Outpatient share of activity	43.2%	44.2%	45.2%	2%	5%
	CMI/OP adjusted admissions	103,149	108,184	102,512	-5%	-1%
	Payer mix (% of charges):					
	Commercial	43.8%	42.7%	43.2%	0.5%	-0.6%
	Medicare	31.6%	32.3%	31.3%	-1.0%	-0.3%
	Medicaid	19.8%	20.1%	22.3%	2.2%	2.5%
$\rightarrow$	Non-sponsored	4.8%	4.9%	3.2%	-1.7%	-1.6%
	Total	100.0%	100.0%	100.0%	0.0%	0.0%



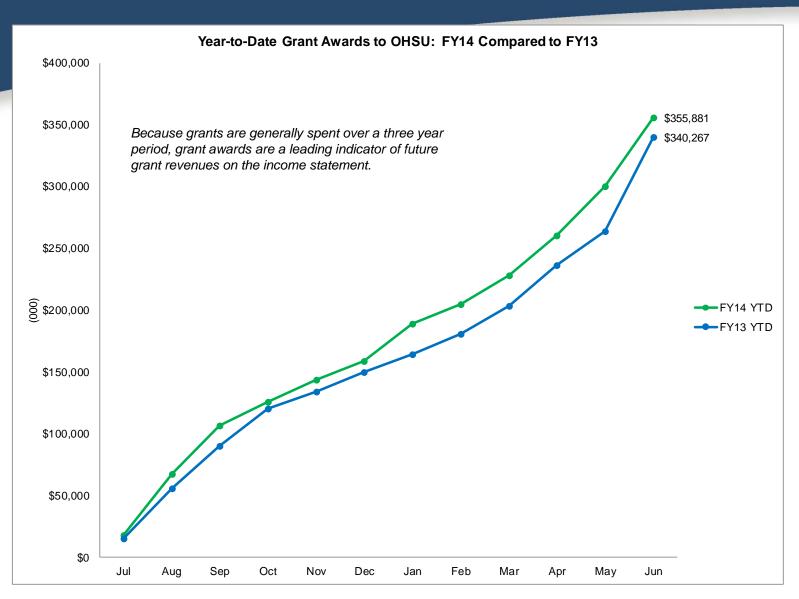
# Uninsured Covered by Medicaid with ACA



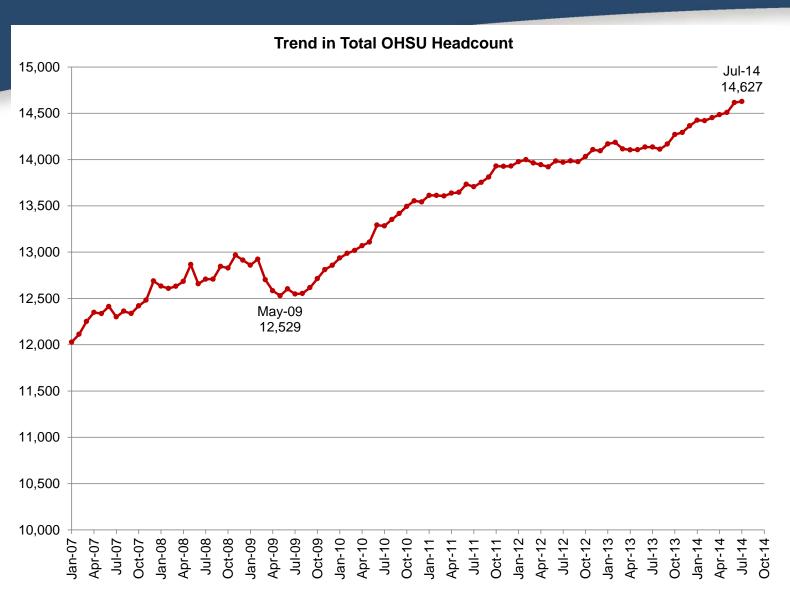
# **ACA Coverage Funded Half by Payment Cuts**



### **Grant Awards 4.6% Above Last Year**



# 2,100 Jobs Created Since Financial Crisis



### FY14 Results with Foundations Consolidated

- OHSU's audited financial statements include consolidating tables that add the financial results of the OHSU Foundation and Doernbecher Children's Hospital Foundation to the OHSU total university or public corporation results reported here.
- These consolidated financials include eliminating entries between the university and the Foundations, as well as reclassifying State appropriations to non-operating items, consistent with government accounting (GASB GAAP).
- Operating income at the Foundations swings widely from year to year, as very large gifts (such as the Knight Cancer and Cardiovascular Institute pledges) are received in one period, then transferred up to the University for expenditure in subsequent years.
- In addition, consolidated investment income (which is marked to market) varies significantly with general movement of the stock and bond markets.
- The table on the following page shows these components for the consolidated bottom line for the past 3 years. Net income in FY13 included the benefit of the Knight Cardiovascular Institute gift, while FY14 includes the benefit of a strong stock market.



# Foundation-Consolidated Net Income \$192M

(millions)	FY12	FY13	FY14
OHSU operating income	\$83	\$99	\$90
Foundations operating income Restricted capital elimination Reclass of State appropriations	(36) (4) (35)	57 (1) (30)	(7) 16 (35)
Consolidated operating income	8	125	63
State appropriations Investment & other nonoperating	35 20	30 51	35 94
Consolidated net income	<del></del>	\$207	\$192



# **FY15 July Results**

- The next page summarizes operating income from the first month of FY15, following the new presentation of "patient care" and "research & education", rather than the prior "hospital" and "other university" columns.
- On strong volume, income from patient care is running \$1 million above target, while research & education is \$(2) million off, for a net \$(1) million gap to expected run-rate.
- This is not unusual during the early months of the year, with slow grant and tuition revenues during the summer and typical delays in drawing gift funds from the Foundations.
- In addition, the School of Dentistry incurred one-time costs from their move into the CLSB/Skourtes Tower and a change in providing equipment to students.
- Finally, we are working to improve productivity and performance in the Department of Pediatrics, which has been running off budget for a number of months.



# FY15 July Results \$(1)M Off Target

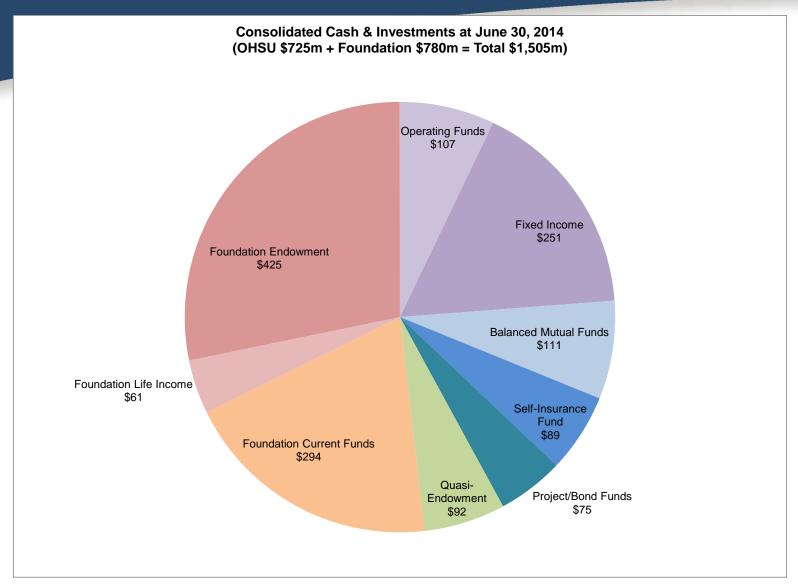
FY15 July Results (1 month)	Patient	Research & Education	Total
(millions)	Care		OHSU
FY15 Annual Budget: Revenue Expense Operating income	\$1,784	\$602	\$2,386
	<u>1,734</u>	<u>582</u>	<u>2,316</u>
	50	20	70
FY15 Monthly Budget: Revenue Expense Operating income	148.7	50.2	198.8
	<u>144.5</u>	<u>48.5</u>	<u>193.0</u>
	4.2	1.7	5.8
FY15 July Actual: Revenue Expense Operating income	150.9	41.1	192.0
	<u>145.7</u>	<u>41.6</u>	<u>187.3</u>
	5.2	(0.5)	4.7
Variance from Monthly: Revenue Expense Operating income	2.2	(9.0)	(6.8)
	<u>1.2</u>	(6.9)	(5.7)
	\$1.0	\$(2.1)	\$(1.1)



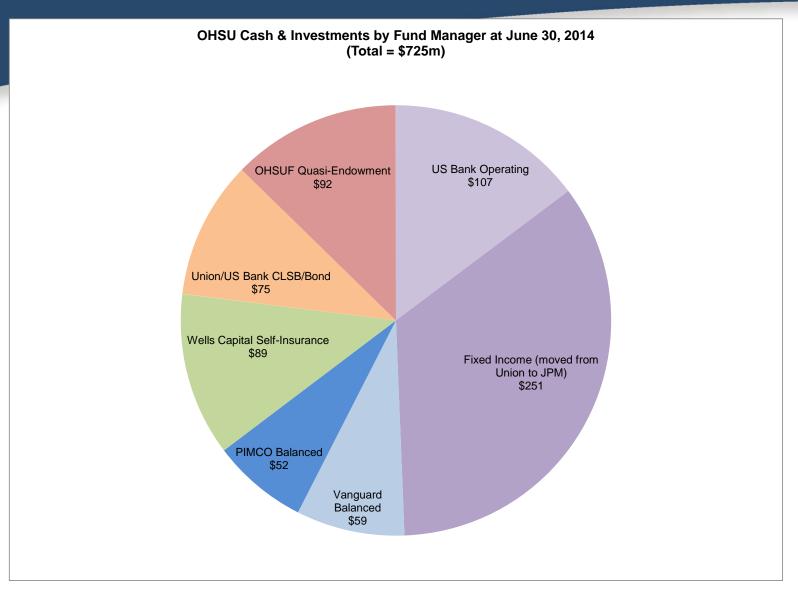
### **FY14 Investment Performance**

- For the first time, consolidated cash & investments exceeded \$1.5 billion, with \$725 million directly on OHSU's books and \$780 million at the Foundations, mostly endowment and unexpended gift funds.
- The \$725 million of OHSU cash & investments returned 4% or \$29 million, slightly above benchmark.
- Solid returns were helped by repositioning during the year of fixed income investment management to JP Morgan, as well as the balanced mutual fund positions established in FY12.
- In particular, the \$50+ million in the Vanguard 60% stock / 40% bond index fund returned 16.5%, with daily liquidity and very low fees.
- We are now turning attention to optimizing the smaller pools, including capital and debt service reserve funds, and projecting better our daily cash needs, where currently we secure a higher return on compensating balances applied to bank fees than from short-term interest rates.

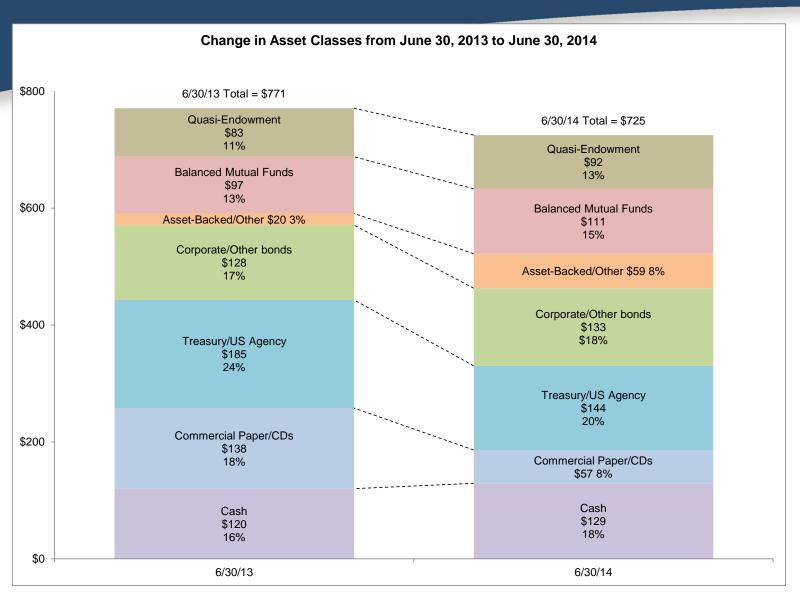
# Consolidated Investments Top \$1.5B



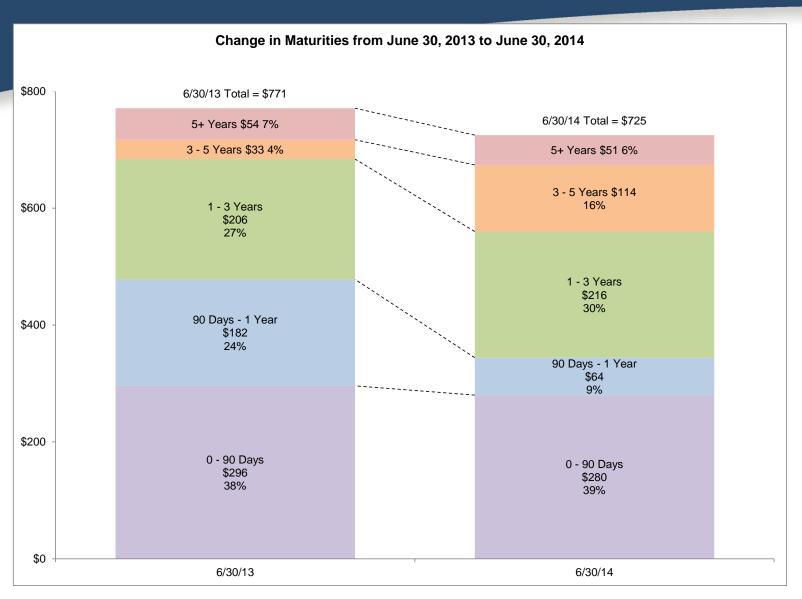
### OHSU-Held Cash & Investments at \$725M



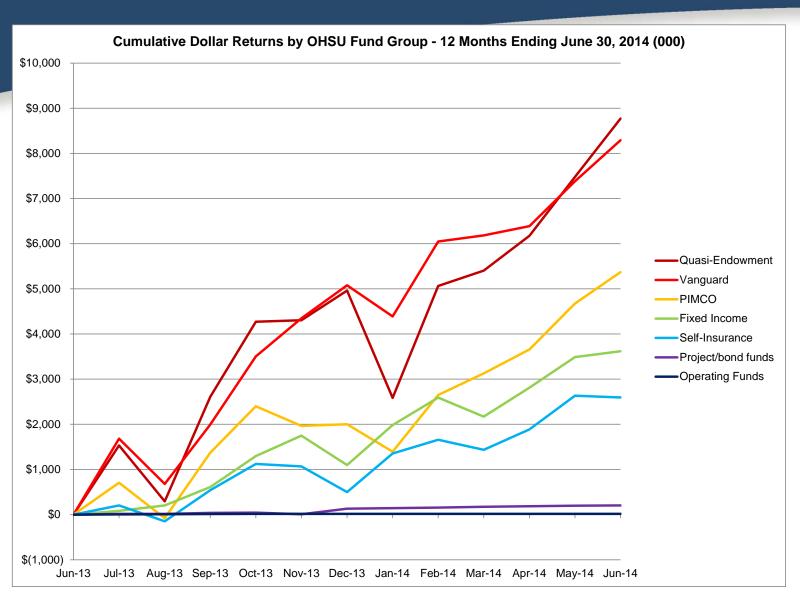
# Repositioning of Asset Mix During FY14



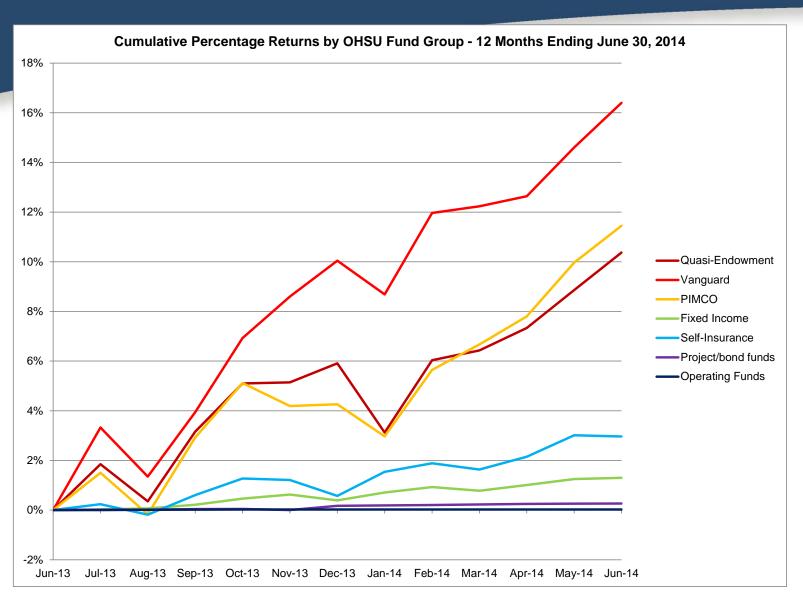
# Repositioning of Maturities During FY14



### **Cumulative Dollar Returns in FY14**



### **Cumulative Percentage Returns in FY14**

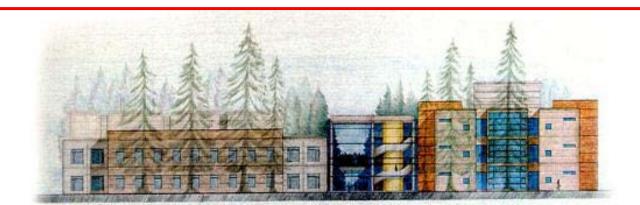




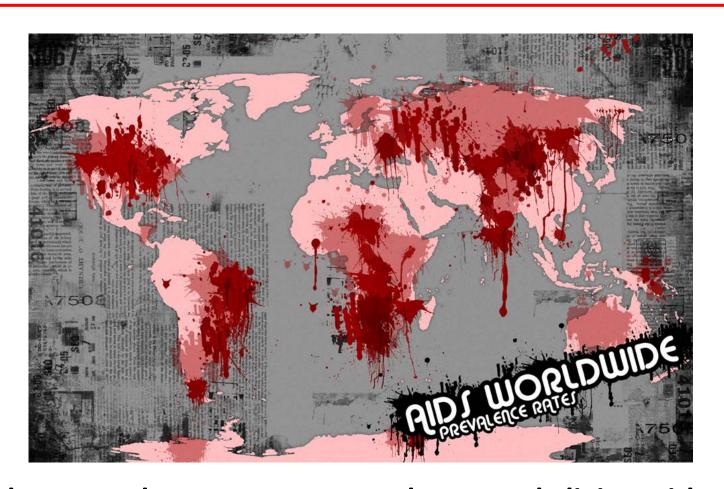


# OHSU and The End of AIDS: "Bench to Bedside" Development of Effective Preventative and Therapeutic HIV Vaccine at OHSU's Vaccine and Gene Therapy Institute

Louis J. Picker, M.D. Vaccine and Gene Therapy Institute Oregon Health & Science University



Even in the era of effective anti-retroviral therapy, there were still 2.1 million new HIV infections, and ~1.5 million AIDS deaths in 2013 . . .



And there are almost as many people currently living with HIV (35 million) as have died from HIV since the start of the epidemic (39 million)

### A New Concept in Vaccine Development: Development of "Effector Memory" Vaccines with Cytomegalovirus (CMV) Vectors



Louis Picker



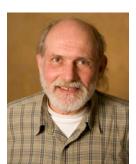
Jay Nelson



Klaus Früh



Scott Hansen



Mike Axthelm



Patrizia Caposio Dan Streblow





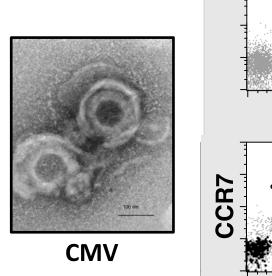
Jonah Sacha

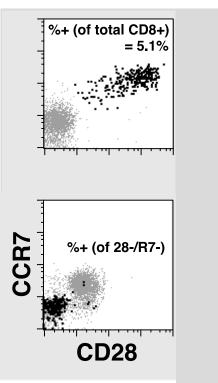




**Oregon National Primate Research Center** 

#### **CMV-specific T cells**





Starting in the late 1990's, a comparative analysis of immune responses to different human viruses led me to conclude that one virus, Cytomegalovirus (CMV) was very different from the others.

The T cells elicited by CMV were extraordinarily high frequency, widely distributed in both lymphoid and nonlymphoid tissues, effector differentiated, and maintained for life . . .

In effect, these large populations of CMV-specific T cells were perpetually "armed and ready" to confront their targets . . . And thus able to mediate continuous, efficient immune surveillance!

In theory, these characteristics would be ideal for a vaccine against pathogens that have evolved to evade slowly developing conventional immune responses . . . in particular HIV and its simian counterpart SIV.

1 R01 AI 060392-01 (Picker) NIH/NIAID

04/01/04 - 03/31/09 \$2,290,393 total direct costs

Development of RhCMV Vectors for SIV Infection

The major goal of this project is to construct RhCMV vectors expressing SIV antigens and assess the efficacy of these vectors in protecting against pathogenic SIV infection.

Starting with a single R01 grant from the NIH in 2004 . . .

#### We used the SIV-rhesus macaque model to emphatically prove our point:

#### medicine

Effector memory T cell responses are associated with protection of rhesus monkeys from mucosal simian immunodeficiency virus challenge

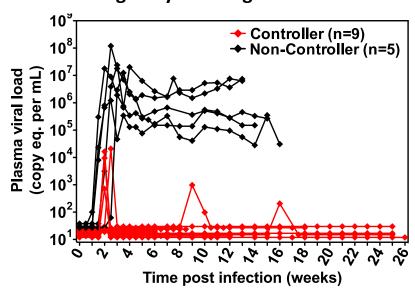
Scott G Hansen<sup>1</sup>, Cassandra Vieville<sup>1</sup>, Nathan Whizin<sup>1</sup>, Lia Coyne-Johnson<sup>1</sup>, Don C Siess<sup>1</sup>, Derek D Drummond<sup>1</sup>, Alfred W Legasse<sup>1</sup>, Michael K Axthelm<sup>1</sup>, Kelli Oswald<sup>2</sup>, Charles M Trubev<sup>2</sup>, Michael Piatak Jr<sup>2</sup>, Jeffrey D Lifson<sup>2</sup>, Jay A Nelson<sup>1</sup>, Michael A Jarvis<sup>1</sup> & Louis J Picker<sup>1</sup>

doi:10.1038/nature10003

Profound early control of highly pathogenic SIV by an effector memory T-cell vaccine

Scott G. Hansen¹, Julia C. Ford¹, Matthew S. Lewis¹, Abigail B. Ventura¹, Colette M. Hughes¹, Lia Coyne-Johnson¹, Nathan Whizin¹, Kelli Oswald<sup>2</sup>, Rebecca Shoemaker<sup>2</sup>, Tonya Swanson<sup>1</sup>, Alfred W. Legasse<sup>1</sup>, Maria J. Chiuchiolo<sup>3</sup>, Christopher L. Parks<sup>3</sup>, Michael K. Axthelm<sup>1</sup>, Jay A. Nelson<sup>1</sup>, Michael A. Jarvis<sup>1</sup>, Michael Piatak Jr<sup>2</sup>, Jeffrey D. Lifson<sup>2</sup> & Louis J. Picker<sup>1</sup>

RhCMV/SIV<sub>F660</sub> vaccinated monkeys (n = 14) Intra-vaginally challenged with SIVmac239



And with this breakthrough, our group, through 2014, has obtained more than 20 government and Foundation grants based on the CMV vector/effector memory T cell vaccine concept, which together include over \$100,000,000 in total awarded funds!

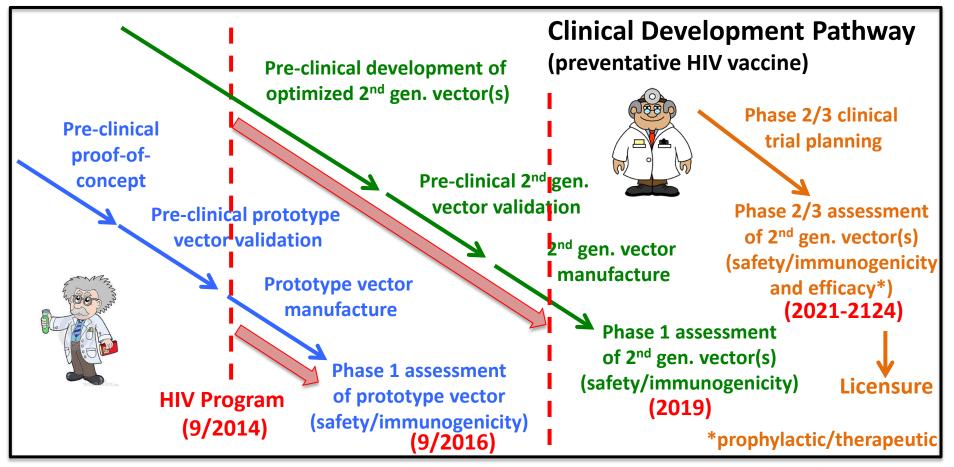
# Culminating in the \$25,000,000 award from the Gates Foundation 2 weeks ago . . .

### OHSU scientist awarded \$25 million grant to further HIV vaccine research

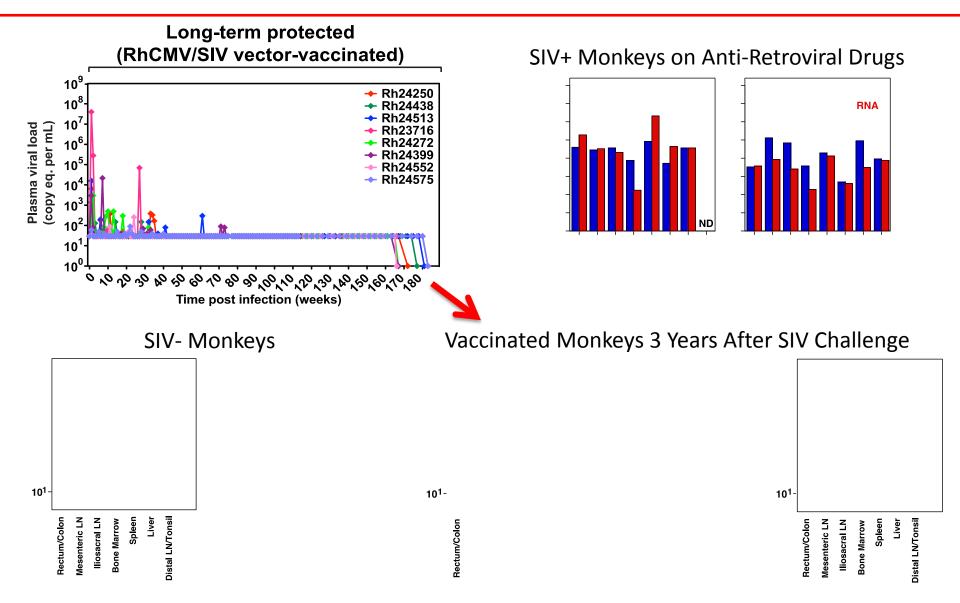
#### 09/03/14 Portland, Ore.

Grant will bolster research led by Louis Picker on vaccine candidate that successfully fights similar virus in monkeys

Oregon Health & Science University researchers have received a \$25 million grant from the Bill & Melinda Gates Foundation to advance work on a promising vaccine candidate that may someday prevent or cure infection with HIV, the virus that causes AIDS.



Perhaps the most remarkable aspect of our work to date is the finding that not only do CMV vector-elicited T cell responses control SIV infection, but they actually eliminate it over time . . .





# Thus, for the first time, a vaccine-elicited immune response has been able to clear a highly aggressive, AIDS-causing virus!

#### Immune clearance of highly pathogenic SIV infection

Scott G. Hansen<sup>1</sup>\*, Michael Piatak Jr<sup>2</sup>\*, Abigail B. Ventura<sup>1</sup>, Colette M. Hughes<sup>1</sup>, Roxanne M. Gilbride<sup>1</sup>, Julia C. Ford<sup>1</sup>, Kelli Oswald<sup>2</sup>, Rebecca Shoemaker<sup>2</sup>, Yuan Li<sup>2</sup>, Matthew S. Lewis<sup>1</sup>, Awbrey N. Gilliam<sup>1</sup>, Guangwu Xu<sup>1</sup>, Nathan Whizin<sup>1</sup>, Benjamin J. Burwitz<sup>1</sup>, Shannon L. Planer<sup>1</sup>, John M. Turner<sup>1</sup>, Alfred W. Legasse<sup>1</sup>, Michael K. Axthelm<sup>1</sup>, Jay A. Nelson<sup>1</sup>, Klaus Früh<sup>1</sup>, Jonah B. Sacha<sup>1</sup>, Jacob D. Estes<sup>2</sup>, Brandon F. Keele<sup>2</sup>, Paul T. Edlefsen<sup>3</sup>, Jeffrey D. Lifson<sup>2</sup> & Louis J. Picker<sup>1</sup>

If CMV vectors can eliminate SIV in the setting of preventative vaccination, it's possible that these vectors could do the same as a therapeutic vaccine for already SIV+ animals on antiretroviral therapy . . . . and if we can cure SIV+ monkeys . . .



#### Why not HIV+ people?

We believe that our CMV vector technology will be a critical component of an HIV cure, giving us a once in a generation opportunity to make a huge difference to global health: the end of AIDS!

We are thus organizing and hoping to fund . . .

# A New Initiative: An HIV Cure Program at OHSU

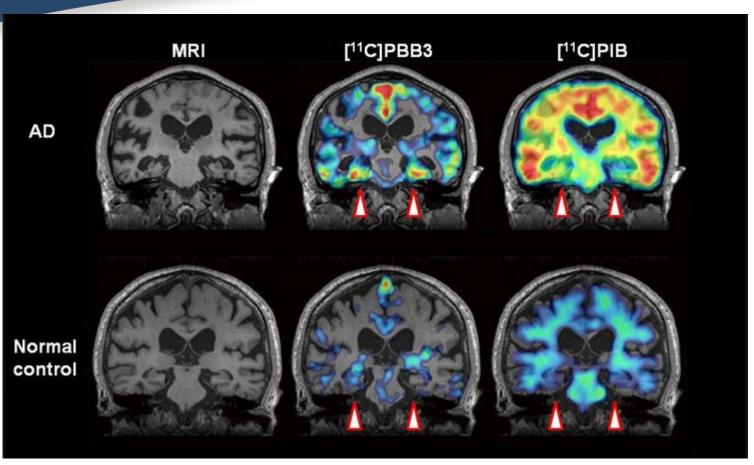
A 10 year "Manhattan" Project to Develop Curative Therapy for HIV/AIDS



# The OHSU Radiochemistry Research Center (RCRC): Vision and Opportunities

William Rooney, PhD
Senior Scientist and Director
Advanced Imaging Research Center

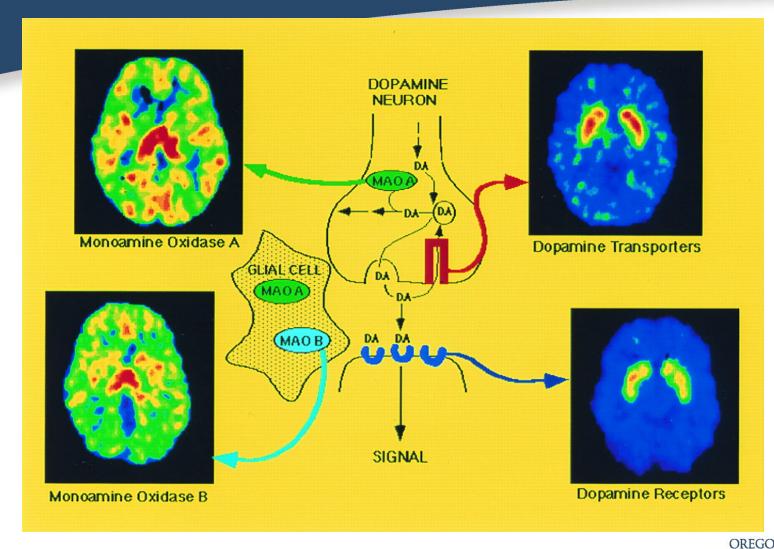
### Molecular imaging of Alzheimer's disease



Maruyama et al, 2013



# Molecular Imaging via <a href="Positron Emission Tomography">Positron Emission Tomography</a> (PET)



Volkow N D et al. PNAS 1997;94:2787-2788

# Sophisticated Chemistry Enables PET Molecular Imaging

<sup>11</sup>C clorgyline

<sup>11</sup>C deprenyl

<sup>11</sup>C methylphenidate

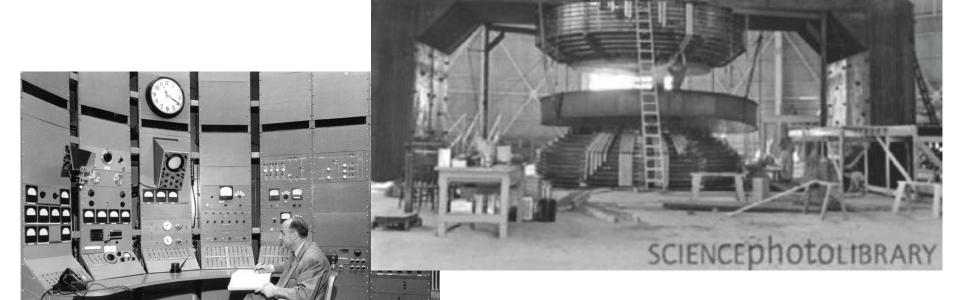
$$\mathbb{C}_{\mathrm{CO_2CH_3}}^{\mathrm{H}}$$

$$\begin{array}{c|c} CI & OH & O \\ \hline \\ CI & H & H \\ \hline \\ CI & 11 \\ \hline \\ CH_3 & CH_3 \\ \end{array}$$

<sup>11</sup>C raclopride



### Cyclotrons have some history





### Primary hardware components of the RCRC

#### Cyclotron - isotope generation

Isotope	half- life (min)	Maximum positron energy (MeV)	Positron range in water (FWHM in mm)	Production method
<sup>11</sup> C	20.3	0.96	1.1	cyclotron
13 <sub>N</sub>	9.97	1.19	1.4	cyclotron
15 <sub>O</sub>	2.03	1.70	1.5	cyclotron
18 <sub>F</sub>	109.8	0.64	1.0	cyclotron



#### Radiochemistry/Radiopharmacy

<sup>18</sup>FDG, <sup>18</sup>FMISO, <sup>11</sup>C-PBB3

<sup>13</sup>NH<sub>3</sub>, <sup>15</sup>OH<sub>2</sub>

Tracer administration/subject monitoring

#### **Advanced Imaging Technologies**

Acquisition, archiving, and processing for clinical, pre-clinical, and other samples







### Hardware is important, but people are crucial



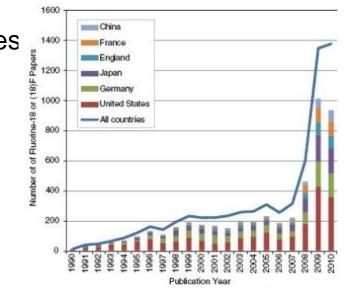
Jeanne Link, PhD



Kenneth Krohn, PhD

#### Areas that will benefit from RCRC capabilities

- Neuroscience, Neurology
- Cardiology
- Cancer
- Endocrinology
- Infectious disease
- Immunology
- Pathology

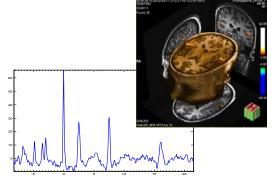


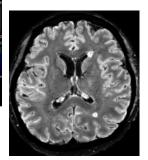
Assuring a Future in US-Based Nuclear UNIVERSITY and Radiochemistry Expertise, 2012

# OHSU has significant capabilities in advanced imaging technologies

Advanced Imaging Research Center (AIRC)



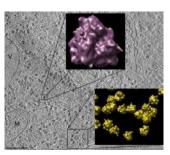




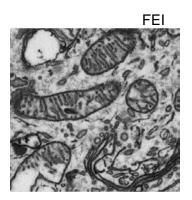
3 T MRI 7 T MRI 11.75 T MRI 8.5 T NMR/MRI 3T MRI ONPRC

#### OHSU Center for Spatial Systems Biomedicine (OCSSB)





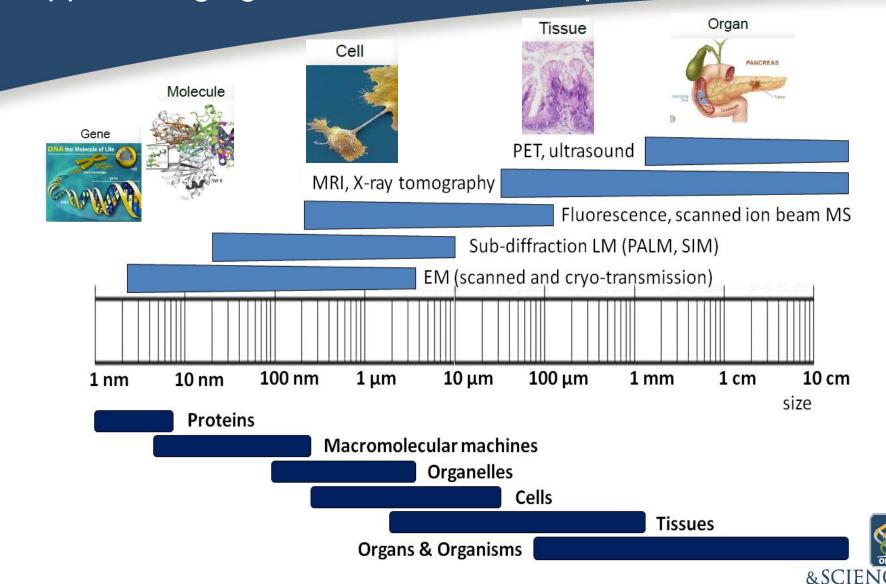
FEI



Titan Krios Helios Nanolab Technai PALM

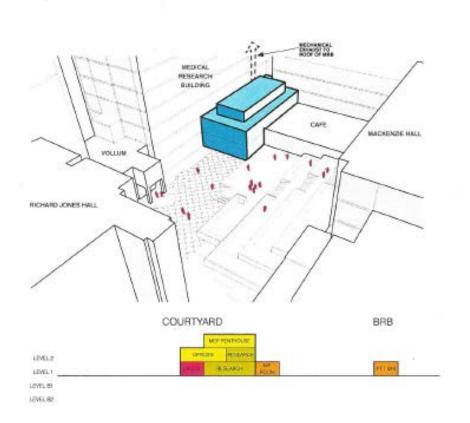


# OHSU has deployed a range of technologies that support imaging over a tremendous spatial scale



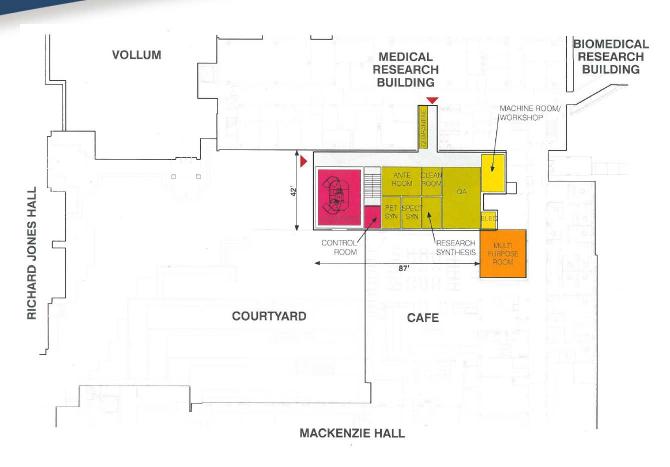


## The RCRC Program

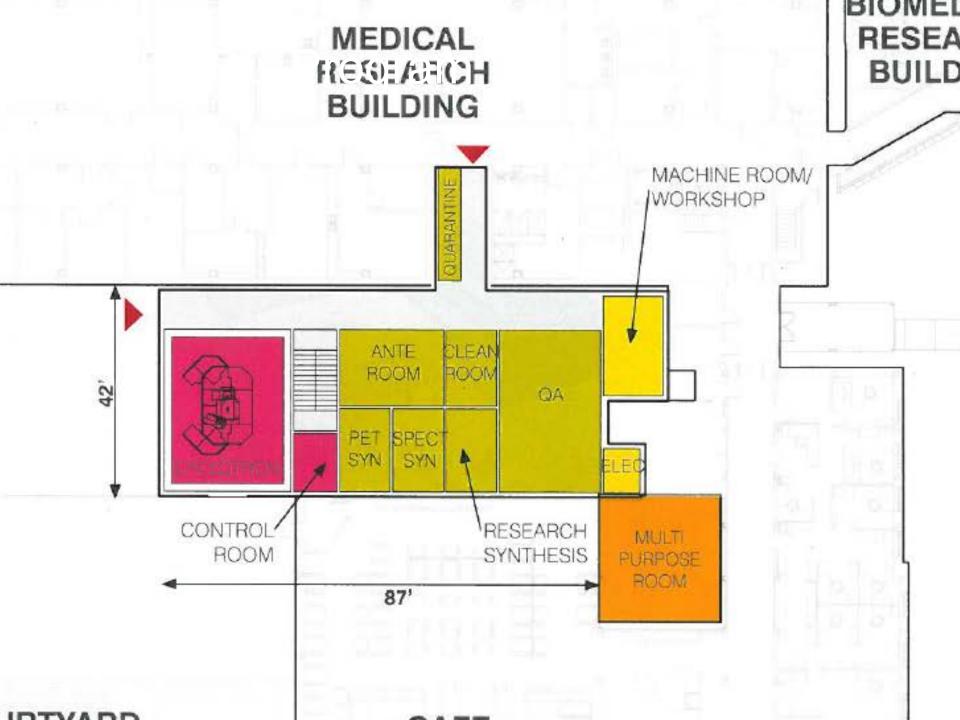


## **OPTION 4:** NO COMMERCIAL LEVEL B1: 3,800 GSF TOTAL: 7,980 GSF function. The remaining program is placed synthesis labs for research. Level two houses of the Commercial Partner and one cyclotron.

# The RCRC Program







# THE KNIGHT CANCER CHALLENGE

#### HOW MUCH RAISED? More than \$431 million\*

of the \$500 million needed by February 4, 2016, World Cancer Day, to activate an additional \$500 million gift from Nike co-founder Phil Knight and his wife, Penny.

#### HOW MANY DONORS? A lot.

6,296+ donors to date from all 50 states, the District of Columbia and gifts from outside the United States

#### WHERE FROM? All over.

56 donors from Florida

51 donors from New York

29 donors from Minnesota

25 donors from Texas

8 donors from the United Kingdom

3 donors from Canada

2 donors from Taiwan, Republic of China

#### **HOW MANY \$1 MILLION+ GIFTS?** Thirty five.

6 Anonymous 19 from Oregon

4 from Washington

1 from California

1 from Michigan

1 from Minnesota

2 from New York

1 from Wyoming

76% of donors from Oregon

24% from outside Oregon

#### WHICH ORGANIZATIONS SUPPORT THIS? Here are a few.

American Cancer Society **Dutch Bros Coffee** 

Full Sail Brewing Company

Heathman Hotel Hoffman Construction Company

Hyundai Hope on Wheels

Intel Corporation

Kuni Automotive Leukemia & Lymphoma Society

Newman's Own Foundation

**NW Natural** 

Oregon Community Foundation

Portland Winterhawks Reser Family Foundation Safeway Foundation The Standard United Way Wieden + Kennedy Willamette Dental Group

\*Includes \$200 million from State of Oregon

#### **OHSU Philanthropy**

(non-challenge) FY 2014 and FY 2015 to date (7/1/13 through 8/31/14)

Giving snapshot:

How much raised? - \$134,721,903

How many donors? 13,486

from all 50 states, the District of Columbia and gifts from outside the United States

72% from Oregon

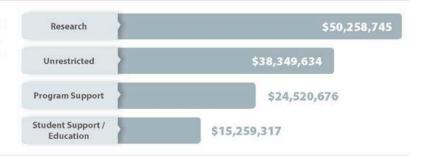
28% from outside of Oregon

#### How many \$1 million+ gifts?

- 22 \$1 million+ gifts
- 14 from Oregon
- 2 from Washington
- 2 from California
- 1 from Illinois
- 3 anonymous

#### Giving by designation

(FY14 and FY15 to date)



Top designations for non-Knight Cancer Challenge gifts \$25 million HIV Vaccine Research \*\$13.9 million Parkinson's Center Support

\$4.8 million Doernbecher Children's Hospital/Pediatrics

\*\$4.1 million Casey Eye Institute

\$4 million Driskill Translational Research Training Program (SOM/neurology)

\*\$4 million Casey Eye Institute for Glaucoma, Macular Degeneration and Indigent Care

\$2.87 million Vaccine and Gene Therapy Institute

\*\$2.4 million 40% to Neurosciences; 40% to OCSSB; 20% OHRC \$2.4 million CEI Oregon State Elks Association Children's Eye Clinic

\*\$2.25 million Center for Ethics in Health Care

\$2.23 Hillion Center for Ethics in realth

\*\$2.12 million Endowed Scholarship

\*\$2 million Endowed Lectureship

\$2 million Surgery Education

\$1.5 million Multiple Sclerosis Research

\$1.5 million Regenerative Medicine – Nerve Regeneration

\$1 million PKAN Forward Research

\$1 million The Campbell Research Laboratory at Casey Eye Institute



<sup>\*</sup> Includes bequest Intentions