

ICMJE DISCLOSURE FORM

Date: 05/October/2023
 Your Name: Richard C Mohs
 Manuscript Title: The HOPE4MCI study: A randomized double-blind assessment of AGB101 for the treatment of MCI due to AD
 Manuscript number (if known): TRCI-D-23-00082R1

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author's relationships/activities/interests as they relate to the current manuscript only.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	National Institute on Aging	Grant R01AG061091 "A Phase 3 Pivotal Trial of AGB101 to Slow Progression in MCI due to Alzheimer's Disease"
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	<u>None</u>	PI for Grant R01AG061091 "A Phase 3 Pivotal Trial of AGB101 to Slow Progression in MCI due to Alzheimer's Disease"
		National Institute on Aging	
3	Royalties or licenses	<u>X</u> None	
4	Consulting fees	<u>None</u>	Global Alzheimer's Platform (GAP) Foundation;
			AgeneBio, Inc.

			Amyriad Therapeutics, Inc. MD Anderson Cancer Center
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input type="checkbox"/> None	Member, Board of Directors for Cogstate, Ltd. Member, Board of Governors, Alzheimer's Drug Discovery Foundation
11	Stock or stock options	<input type="checkbox"/> None	Holder of stock in Eli Lilly and Co.
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 10/10/2023

Your Name: Arnold Bakker

Manuscript Title: The HOPE4MCI study: A randomized double-blind assessment of AGB101 for the treatment of MCI due to AD

Manuscript Number (if known): TRCI-D-23-00082R1

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1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	<input type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <td style="width: 60%;">R01AG061091</td> <td>NIH Grant to Johns Hopkins University</td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td colspan="2" style="text-align: center; font-size: small;">Click the tab key to add additional rows.</td> </tr> </table>	R01AG061091	NIH Grant to Johns Hopkins University			Click the tab key to add additional rows.	
R01AG061091	NIH Grant to Johns Hopkins University							
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Time frame: past 36 months								
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> </table>						
3	Royalties or licenses	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> </table>						

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	<input type="checkbox"/> None	
		AgeneBio, Inc.	Consultant
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input type="checkbox"/> None	
		Science Luncheon Series. UTD Center for Vital Longevity. Dallas, TX	Honorarium for invited lecture.
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	
8	Patents planned, issued or pending	<input type="checkbox"/> None	
		US-2021244709-A1 Methods and compositions for improving cognitive function	Listed inventor
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input type="checkbox"/> None	
		DSMB Member, NIH supported clinical trial: Network-Level Mechanisms for Preclinical Alzheimer's Disease Development (1R21AG056882). Medical College of Wisconsin, Milwaukee WI, USA.	Not compensated.
10	Leadership or fiduciary role in other board, society, committee or	<input checked="" type="checkbox"/> None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
	advocacy group, paid or unpaid		
11	Stock or stock options	<input checked="" type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

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ICMJE DISCLOSURE FORM

Date: 10/7/2023

Your Name: Sharon Rosenzweig-Lipson

Manuscript Title: The HOPE4MCI study: A randomized double-blind assessment of AGB101 for the treatment of MCI due to AD

Manuscript Number (if known): TRCI-D-23-00082R1

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1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	<input type="checkbox"/> None		
		AgeneBio	VP of R&D for AgeneBio (2011-present)	employee/consultant
		NIH U01AG074950; R01AG078769	RO1	
		ADDF		
Time frame: past 36 months				
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None		
3	Royalties or licenses	<input checked="" type="checkbox"/> None		

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	
4	Consulting fees	<input checked="" type="checkbox"/> None	
		AgeneBio	VP of R&D for AgeneBio (2011-present) employee/consultant
		Life Biosciences	CSO for Life Biosciences (2023-present) Consultant (2022-2023)
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input type="checkbox"/> None	
		AgeneBio	CTAD, AAIC
8	Patents planned, issued or pending	<input type="checkbox"/> None	
		BR-112017025031-B1 EP-3590506-A1 OA-18467-A CA-3189302-A1	Listed co-inventor
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	
11	Stock or stock options	<input type="checkbox"/> None	
		AgeneBio	Stock options
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input type="checkbox"/> None	
		AgeneBio	Computer
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

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ICMJE DISCLOSURE FORM

Date: 10/10/2023

Your Name: Michael Rosenblum

Manuscript Title: The HOPE4MCI study: A randomized double-blind assessment of AGB101 for the treatment of MCI due to AD

Manuscript Number (if known): TRCI-D-23-00082R1

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		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	<input type="checkbox"/> None	
		Consulting for Agenebio with consulting company Evolution Trial Design, Inc. (Dr. Rosenblum is president of this consulting company)	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	
		Aforementioned NIH grant reimbursed travel costs for oral presentation at CTAD conference.	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input type="checkbox"/> None	
		Consulting for Agenebio with consulting company Evolution Trial Design, Inc. (Dr. Rosenblum is president of this consulting company)	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	<input checked="" type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

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ICMJE DISCLOSURE FORM

Date: 10/10/2023

Your Name: Russell L. Barton

Manuscript Title: The HOPE4MCI study: A randomized double-blind assessment of AGB101 for the treatment of MCI due to AD

Manuscript Number (if known): TRCI-D-23-00082R1

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NIH/NIDA Grant R01AG048349										
Consulting for AgeneBio by consulting company PharmaSagacity Consulting, LLC										
Russell Barton is president and independent consultant of this consulting company.										
Click the tab key to add additional rows.										
Time frame: past 36 months										
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr><td style="width: 60%; height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> <tr><td style="height: 20px;"></td><td></td></tr> </table>								
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4	Consulting fees	<input type="checkbox"/> None	
		Consulting for AgeneBio by consulting company PharmaSagacity Consulting, LLC Russell Barton is president and independent consultant of this consulting company.	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input type="checkbox"/> None	
		AgeneBio has supported (financially reimbursed) travel to scientific meetings in the past.	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
11	Stock or stock options	<input type="checkbox"/> None	
		Stock options provided by AgeneBio were relinquished	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 10/9/2023

Your Name: Marilyn Albert

Manuscript Title: The HOPE4MCI study: A randomized double-blind assessment of AGB101 for the treatment of MCI due to AD

Manuscript Number (if known): TRCI-D-23-00082R1

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7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>							
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9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%; height: 15px;"></td><td style="width: 50%;"></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> <tr><td style="height: 15px;"></td><td></td></tr> </table>							
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12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

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ICMJE DISCLOSURE FORM

Date: 10/6/2023

Your Name: Sharon Cohen

Manuscript Title: The HOPE4MCI study: A randomized double-blind assessment of AGB101 for the treatment of MCI due to AD

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2	Grants or contracts from any entity (if not indicated in item #1 above).	<input type="checkbox"/> None <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr><td style="width: 70%;">Alnylam</td><td>Research grants paid to institution only.</td></tr> <tr><td>Alzheon</td><td>Research grants paid to institution only.</td></tr> <tr><td>Agene Bio</td><td>Research grants paid to institution only.</td></tr> <tr><td>Alector</td><td>Research grants paid to institution only.</td></tr> <tr><td>Biogen</td><td>Research grants paid to institution only.</td></tr> <tr><td>Cassava</td><td>Research grants paid to institution only.</td></tr> <tr><td>Eisai</td><td>Research grants paid to institution only.</td></tr> <tr><td>Eli Lilly</td><td>Research grants paid to institution only.</td></tr> <tr><td>Janssen</td><td>Research grants paid to institution only.</td></tr> <tr><td>Novo Nordisk</td><td>Research grants paid to institution only.</td></tr> <tr><td>Roche</td><td>Research grants paid to institution only.</td></tr> <tr><td>RetiSpec</td><td>Research grants paid to institution only.</td></tr> </table>	Alnylam	Research grants paid to institution only.	Alzheon	Research grants paid to institution only.	Agene Bio	Research grants paid to institution only.	Alector	Research grants paid to institution only.	Biogen	Research grants paid to institution only.	Cassava	Research grants paid to institution only.	Eisai	Research grants paid to institution only.	Eli Lilly	Research grants paid to institution only.	Janssen	Research grants paid to institution only.	Novo Nordisk	Research grants paid to institution only.	Roche	Research grants paid to institution only.	RetiSpec	Research grants paid to institution only.
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3	Royalties or licenses	<input checked="" type="checkbox"/> None	
4	Consulting fees	<input type="checkbox"/> None	
		Alnylam	Payments to institution only
		Biogen	Payments to institution only
		Cassava	Payments to institution only
		Eisai	Payments to institution only
		Eli Lilly	Payments to institution only
		INmune Bio	Payments to institution only
		Novo Nordisk	Payments to institution only
		ProMIS Neuroscience	Payments to institution only
		Roche	Payments to institution only
		SciNeuro	Payments to institution only
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input type="checkbox"/> None	
		Biogen	No personal fees for advisory board work
		Eisai	No personal fees for advisory board work
		Eli Lilly	No personal fees for advisory board work
		Novo Nordisk	No personal fees for advisory board work
		Roche	No personal fees for advisory board work
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None	
11	Stock or stock options	<input checked="" type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 10/9/2023

Your Name: Scott L Zeger

Manuscript Title: The HOPE4MCI study: A randomized double-blind assessment of AGB101 for the treatment of MCI due to AD

Manuscript Number (if known): TRCI-D-23-00082R1

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

	Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)						
Time frame: Since the initial planning of the work								
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11	Stock or stock options	<input checked="" type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

Please place an "X" next to the following statement to indicate your agreement:

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ICMJE DISCLOSURE FORM

Date: 10/10/2023

Your Name: Michela Gallagher

Manuscript Title: The HOPE4MCI study: A randomized double-blind assessment of AGB101 for the treatment of MCI due to AD

Manuscript Number (if known): TRCI-D-23-00082R1

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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4	Consulting fees	<input type="checkbox"/> None	
		AgeneBio, Inc.	self
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	
8	Patents planned, issued or pending	<input type="checkbox"/> None	
		See attached doc	Institutions
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee, or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None	

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id	title	assignee
US-2021244709-A1	Methods and compositions for improving cognitive function	The Johns Hopkins University
US-10624875-B2	Methods and compositions for treating schizophrenia	The Johns Hopkins University
US-2022218665-A1	Methods and compositions for improving cognitive function	The Johns Hopkins University
US-2022265685-A1	Methods and compositions for improving cognitive function	The Johns Hopkins University
AU-2021200325-B2	Methods and compositions for improving cognitive function	The Johns Hopkins University
US-2008177061-A1	Target for therapy of cognitive impairment	Michela Gallagher, Pauline Kay Lund, Rothstein Jeffrey D
WO-2007019312-A3	Methods for characterizing and treating cognitive impairment in	Univ Johns Hopkins, Michela Gallagher, Rebecca Haberman
BR-112017025031-B1	LEVETIRACETAM EXTENDED RELEASE PHARMACEUTICAL COMPOSITIONS	Agenebio, Inc
US-2014057903-A1	Methods for characterizing and treating cognitive impairment in	The Johns Hopkins University
WO-2014144546-A1	Methods and compositions for improving cognitive function	The Johns Hopkins University
WO-2014078377-A1	Methods and compositions for treating schizophrenia	Agenebio, Inc.
WO-2010105189-A1	Method for identifying compounds that attenuate the function	The Johns Hopkins University
WO-2009139901-A2	Methods and compositions for improving cognitive function	The Johns Hopkins University
US-2005267076-A1	Method for improving cognitive function	Johns Hopkins University
WO-2006034485-A2	Treatment for age-related cognitive decline and other condition	The Johns Hopkins University, University Of North Carolina
US-2006014801-A1	Prevention and treatment of cognitive impairment using (R)-(-)-2	The Johns Hopkins University
EP-3590506-A1	Extended release pharmaceutical compositions of levetiracetam	Agenebio, Inc.
AU-2018208662-A1	Methods and Compositions for Treating Schizophrenia	The Johns Hopkins University
OA-18467-A	Extended release pharmaceutical compositions of levetiracetam	Agenebio, Inc
WO-2014153180-A1	Methods and compositions for improving cognitive function	Michela Gallagher
AU-2013344646-A1	Methods and compositions for treating schizophrenia	The Johns Hopkins University
CA-3189302-A1	Combinations of gabaa alpha 5 agonists and sv2a inhibitors and	Agenebio, Inc., Michela Gallagher, Sharon Rosenzweig-Lipson