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Advancing Manufacture of Cell and Gene
Therapies VII

Proceedings

2-6-2022

Conference Program

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Program

Advancing Manufacture of Cell and Gene Therapies VII

February 6-10, 2022

Loews Coronado Bay Hotel

Coronado, California

Conference Chairs

Sharon Brownlow, Cell & Gene Therapy Catapult, UK

Sean Palecek, University of Wisconsin, USA

Damian Marshall, Achilles Therapeutics, UK

Fernanda Masri, Cell & Gene Therapy Catapult, UK



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4000 Coronado Bay Road
Coronado, California, 92118
Phone: 619-424-4000**

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Engineering Conferences International (ECI) is a not-for-profit global engineering conferences program, originally established in 1962, that provides opportunities for the exploration of problems and issues of concern to engineers and scientists from many disciplines.

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Previous conferences in this series:

Scale-Up and Manufacturing of Cell-Based Therapies

January 11-13, 2012

San Diego, California

Conference Chairs:

Chris Mason, University College London, UK

Lars Nielsen, University of Queensland, Australia

Greg Russotti, Celgene, USA

Scale-Up and Manufacturing of Cell-Based Therapies II

January 21-23, 2013

San Diego, California

Conference Chairs:

Chris Mason, University College London, UK

Lars Nielsen, University of Queensland, Australia

Greg Russotti, Celgene, USA

Scale-Up and Manufacturing of Cell-Based Therapies III

January 5-9, 2014

San Diego, California

Conference Chairs:

Chris Mason, University College London, UK

Greg Russotti, Celgene, USA

Peter Zandstra, University of Toronto, Canada

Scale-Up and Manufacturing of Cell-Based Therapies IV

January 18-22, 2015

San Diego, CA USA

Conference Chairs:

Chris Mason, University College London, UK

Greg Russotti, Celgene Cellular Therapeutics, USA

Peter Zandstra, University of Toronto, Canada

Thomas Brieva, Celgene Cellular Therapeutics, USA

Scale-Up and Manufacturing of Cell-Based Therapies V

January 15-19, 2017

San Diego, California

Conference Chairs:

Thomas Brieva, Celgene Cellular Therapeutics, USA

Chris Mason, University College London, UK

William Miller, Northwestern University, USA

Scale-Up and Manufacturing of Cell-Based Therapies V

January 27-31, 2019

San Diego, California

Conference Chairs:

Dolores Baksh, GE Healthcare

Ivan Wall, Aston University

Rod Rietze, Novartis

Christopher Hewitt Outstanding Young Investigator Award



Andy Tay Kah Ping, Imperial College London/National University of Singapore

ECI is pleased to announce that Andy Tay Kah Ping is the winner of the first Christopher Hewitt Outstanding Young Investigator Award.

Andy Tay graduated in 2014 from NUS with a First-Class Honors in Biomedical Engineering. He later headed to the University of California, Los Angeles for his PhD studies and graduated in 2017 as the recipient of the Harry M Showman Commencement Award. As a PhD student, Andy also received the Helmsley Fellowship, Toshihiko Tokizane Memorial Award, Springer Thesis Prize and MRS Bulletin Postdoc Publication Prize.

Andy later received his postdoctoral training at Stanford University before heading to Imperial College London as an 1851 Royal Commission Brunel Research Fellow. For his research developing novel materials for biomedical applications, Andy is listed as a 2019 Forbes 30 Under 30 (US/Canada, Science), 2020 World Economic Forum Young Scientist, and 2020 The Straits Times '30 and Under' Young Singaporeans to Watch.

Andy is currently a Presidential Young Professor in NUS where he is leading a lab to develop technologies for immuno-engineering. There are three main thrusts in his lab including immune cell engineering, immune organ regeneration and immuno-stimulatory micro-robots for drug delivery.

Besides research, Andy is highly passionate in science mentoring and outreach. He has published in Nature, Science and The Scientist among others. For his commitment in evidence-based science communication, he has received the Highly Commended Runner-Up for the Queen's Young Leader Award, Travel Fellowship from Universcience (the largest European science museum) and a Visiting

Fellowship from the Museum of Arts and Sciences Sydney. He was also a Creativity in Research Scholar at Stanford University Design School where he created toy kits to better explain cancer immunotherapy for children going for clinical trials.

You can visit his lab webpage here: andytaykp.com

About this Award

This award is in honor of Christopher Hewitt. He was a leading biological engineer, distinguished for his research using flow cytometry and cell sorting to understand the interaction of the cell with the bioreactor environment within such diverse areas as microbial fermentation, bio-remediation, bio-transformation, brewing and cell culture. He was also the co-founder of the Centre for Biological Engineering at Loughborough University, where he developed a world-leading team in regenerative medicine bioprocessing. In particular, his team made a significant contribution to the literature on the culture and recovery of fully functional human mesenchymal stem cells in stirred bioreactors based on sound biochemical engineering and fluid dynamic considerations essential to scale-up for commercialization. In recognition of his achievements, he was elected Fellow of the Royal Academy of Engineering in 2018. Chris Hewitt was an active contributor to the ECI conference series “Advancing Manufacturing for Cell based and Gene Based Therapies”. We will miss him. This is the first time this award will be presented.

The award is given to a promising young scientist whose work shows exceptional promise in the field of process development of cell based and gene based therapies. The award includes the opportunity to make a presentation at the conference.

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Pall Corporation

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Locations and Notes

- *Technical sessions will be in the Commodore CDE. Poster Sessions will be in the Bay Pavilion.*
- *Breakfast bites will be in Commodore AB and the Commodore Foyer. Lunches and dinners will be in the Bay Pavilion.*
- *The ECI on site office will be in the Sovereign Room (2nd floor).*
- *The Boardroom (2nd floor) will be available for ad hoc meetings. See ECI staff to reserve a time.*
- *Please wear your mask except when giving a presentation or actively eating or drinking. Please maintain physical distancing as much as possible.*
- *Audio, still photo and video recording by any device (e.g., cameras, cell phones, laptops, PDAs, watches) is strictly prohibited during the technical sessions, unless the author and ECI have granted prior permission.*
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- *Emergency Contact Information: Because of privacy concerns, ECI does not collect or maintain emergency contact information for conference participants. If you would like to have this information available in case of emergency, please use the reverse side of your name badge.*

Sunday, February 6, 2022

- 08:30 – 09:00 Preconference Workshop Check-in
- 09:00 – 16:30 **Preconference Workshop**
How Can Analytics Enable Manufacturing Automation, Process Robustness, and Deliver Patient Access to Life-Saving Cell-Based Therapies?
- Workshop Chairs: Nina Bauer, Millipore Sigma, USA
 Carolyn Yeago, Georgia Institute of Technology, USA
 Thomas Heathman, Ori Biotech North America, USA
- 14:30 **Conference Check-in**
- 16:45 – 17:00 Conference welcome by the Conference Chairs and Liaison
- Conference opening ceremony**
ECI Liaison: Barry Buckland (NIIMBL, USA)
- Conference Chairs: Sharon Brownlow, Cell & Gene Therapy Catapult, UK
 Sean Palecek, University of Wisconsin, USA
 Damian Marshall, Achilles Therapeutics, UK
 Fernanda Masri, Cell & Gene Therapy Catapult, UK
- Student Liaison: Aaron Simmons (PhD Student, Palecek Lab - Chemical and Biological Engineering, University of Wisconsin-Madison)
- 17:00 – 18:00 **Plenary fireside chat**
Where is the cell and gene therapy field heading and how can we increase patient access?
- Host:** Sean Palecek, University of Wisconsin, USA
- Panelists:** Phil Vanek, Gamma Biosciences, USA
 Boro Dropulic, Caring Cross, USA
 Krishnendu Roy, Georgia Institute of Technology, USA
 Gregory Russotti, Century Therapeutics, USA
- 18:30 – 21:00 Welcome Dinner and Networking (Pavilion)
Sponsored by Bayer

Monday, February 7, 2022

- 07:30 – 09:00 Bites for Breakfast with Sponsors
- Advances in Viral Vector Manufacturing**
Sponsored by Pall Corporation
Chairs: Paula Alves, iBET, Portugal
Sven Ansorge, ExCellThera, Canada
- 09:00 – 09:40 **Plenary Presentation**
Directed evolution of novel AAV vectors for clinical gene therapy
David Schaffer, University of California, Berkeley, USA
- 09:40 – 10:00 **Integrated end-to-end MVA viral vector production: Perfusion culture shows economical advantage over batch culture**
Gwendal Gränicher, Max Planck Institute, Germany
- 10:00 – 10:20 **Process economics evaluation of Adeno-associated Viral Vector (AAV) manufacturing**
Annabel Lyle, University College London, United Kingdom
- 10:20 – 10:40 **Developing a suspension transfection platform to produce adeno-associated viruses**
Kory Blocker, University of Pennsylvania, USA
- 10:40 – 11:00 **Q&A Panel**
- 11:00 – 11:45 Coffee Break (***Sponsored by Mission Bio***)
- 11:45 – 12:05 **Scalable downstream purification of recombinant adeno-associated viral vectors**
Sarah Blackmore, Pall, USA
- 12:05 – 12:25 **Industrialization of the GMP manufacture of exosome therapeutics and opportunities for further multifold process productivity increase**
Konstantin Konstantinov, Codiak BioSciences, USA
- 12:25 – 13:05 **Q&A Panel**
- 13:05 – 14:40 Lunch & Networking (Pavilion)
- 14:40 – 15:00 **Considerations of manufacturability for AAV based gene therapy products for rare diseases**
Nripen Singh, Passage Bio, USA
- 15:00 – 15:20 **Process development of a serum-free and scalable lentiviral vector manufacturing platform for cellular immunotherapies**
Carme Ripoll Fiol, University College London, United Kingdom
- 15:20 – 15:40 **A dual platform revolutionizing gene therapy manufacturing**
Tania Pereira Chilima, Univercells Technologies, Belgium
- 15:40 – 16:00 **Q&A Panel**

Monday, February 7, 2022 (continued)

16:00 – 16:20

Poster snapshot presentations

- 5 **An efficient microcarrier based Adeno-associated virus production method**
Brian Ladd, KTH, Royal Institute of Technology, Sweden
- 8 **Enhancing rAAV production by HEK293 cells via metabolic profiling**
Michela Pulix, University of Manchester, United Kingdom
- 12 **Continuous production of lentiviral vectors using a fixed-bed bioreactor**
Dale Stibbs, University College London, United Kingdom

18:30 – 20:00

Dinner (Pavilion)

20:00 – 21:30

Poster session and networking drinks
(Sponsored by BioCentriq and Cytiva)

Tuesday, February 8, 2022

- 07:30 – 09:00 Bites for Breakfast with Sponsors
- Advances in Cell Therapy Manufacturing**
Sponsored by PBS Biotech
Chairs: Jo Mountford, University of Glasgow, United Kingdom
Masahiro Kino-oka, Osaka University, Japan
- 09:00 – 09:40 **Plenary Presentation**
Disruptive technologies for cell therapy manufacturing
Jen Moody, Pall Biotech, Canada
- 09:40 – 10:00 **Scalable downstream process development and manufacturing in cGMP for human iPSC derived products**
Sho Sato, Fujifilm Cellular Dynamics, USA
- 10:00 – 10:20 **Key drug product considerations for iPSC-derived NK cell therapies**
Lavanya Peddada, Century therapeutics, USA
- 10:20 – 10:40 **Q&A Panel**
- 10:40 – 11:25 Coffee Break (***Sponsored by Fujifilm Cellular Dynamics***)
- 11:25 – 11:45 **Challenges and solutions for allogeneic cell therapy manufacturing**
Brian Lee, PBS Biotech, Inc., USA
- 11:45 – 12:05 **Advanced manufacturing process design for Mesenchymal Stromal Cell therapies**
Bryan Wang, Georgia Institute of Technology, USA
- 12:05 – 12:25 **Overcoming cell therapy manufacturing barriers through innovation and partnership**
Rupa Pike, Thermo Fisher, USA (**Virtual**)
- 12:25 – 12:45 **Q&A Panel**
- 12:45 – 13:05 **Poster snapshot presentations**
- 17 **Developing an effective scale-down model for a suspension adapted Hek293t-derived lentiviral vector stable producer cell line**
Hamza Patel, University College London, United Kingdom
- 22 **Towards an integrated bioprocess for scalable production and isolation of MSC-derived extracellular vesicles for cardiac repair**
Marta Costa, iBET, ITQB-NOVA, Portugal
- 23 **Developmental lineage of human pluripotent stem cell-derived cardiac fibroblast affects their functional phenotype**
Martha Floy, University of Wisconsin-Madison, USA
- 13:05 – 14:30 Lunch & Networking (Pavilion)

Tuesday, February 8, 2022 (continued)

Gene Editing and Emerging Technologies

Chairs: Ricardo Baptista, Procella Therapeutics AB, Sweden
Krishanu Saha, University of Wisconsin, USA

- 14:30 – 14:50 **Extra cellular vesicles separation and biophysical characterization**
Alois Jungbauer, University of Natural Resources and Life Sciences, Austria
- 14:50 – 15:10 **Process and analytical development challenges for the incorporation of gene edits into T cell therapies**
Thomas Brieva, Tmunity Therapeutics, USA
- 15:10 – 15:30 **Development of autologous adipose derived mesenchymal stem cell therapy: Lessons learned from treating more than 250 patients**
Allan Dietz, Mayo Clinic, USA
- 15:30 – 15:50 **Q&A Panel**
- 15:50 – 16:35 Coffee Break (*Sponsored by Halo Labs*)
- 16:35 – 16:55 **Journey to commercialization of a complex, biological ancillary material**
Lili Belcastro, Bristol Myers Squibb, USA
- 16:55 – 17:15 **Virus-Free CRISPR CAR T cells induce solid tumor regression**
Lauren Sarko, University of Wisconsin, USA
- 17:15 – 17:35 **Q&A Panel**
- 17:35 – 17:38 **Poster snapshot presentation**
- 1 **Manufacturing of gene-modified human mesenchymal stromal cells in microcarriers and agitated conditions**
Pedro Silva Couto, University College London, United Kingdom
- 18:30 – 22:00 **Social event – Boat party**

Wednesday, February 9, 2022

- 07:30 – 09:00 Bites for Breakfast with Sponsors
- Analytics and Big Data**
Chairs: Behnam Ahmadian Baghbaderani, Lonza, USA
Boyan Yordanov, Scientific Technologies, United Kingdom
- 09:00 – 09:40 **Plenary Presentation**
Cell Therapy Analytics: Challenges and Opportunities
Somayeh Tarighat, Genentech, USA
- 09:40 – 10:00 **Integrated intracellular organization and reorganization of the human stem cell**
Susanne Rafelski, Allen Institute, USA
- 10:00 – 10:20 **Digital path to Industry 4.0: The role of data sciences in the cell & gene therapy space**
Marc-Olivier Baradez, Cell and Gene Therapy Catapult, United Kingdom (Virtual)
- 10:20 – 11:00 **Q&A Panel**
- 11:00 – 11:45 Coffee Break (*Sponsored by MaxCyte*)
- 11:45 – 12:05 **Assessing interaction networks within iPSC expansion bioprocessing to elucidate complexities of cellular phenotype and develop advanced process control strategies**
James Colter, University of Calgary, Canada (Virtual)
- 12:05 – 12:25 **Hybrid modeling approaches for autologous cell therapy process characterization**
Mridul Dalmia, Rutgers University, USA
- 12:25 – 12:45 **Q&A Panel**
- 12:45 – 13:05 **Poster snapshot presentations**
- 37 **Systems-level discovery of quality attributes and candidate pathways for optimized production of human pluripotent stem cell-derived cardiomyocytes**
Aaron Simmons, University of Wisconsin, USA
- 38 **Development of analytical assays for the characterization of gene circuit enabled cell therapies**
Brett Kiedaisch, Senti Biosciences, USA
- 39 **Transitioning cell-based processes towards scalable production**
Isobelle Espiritu, ViaCyte, Inc, USA
- 40 **Process development for improved Car-t production utilizing an automated perfusion stirred-tank bioreactor**
Tiffany Hood, University College London, United Kingdom
- 13:05 – 14:20 Lunch & Networking (Pavilion)

Wednesday, February 9, 2022 (continued)

- 14:20 – 15:00 **Chris Hewitt Award Lecture**
Electroporative Nano-Structures for Centrifuge-free and Efficient Immune T-cell Transfection
Andy Kah Ping Tay, NUS, Singapore (**Virtual**)
- The Future of Product Release**
Chairs: Lorraine Borland, Sartorius Stedim, United Kingdom
 Azadeh Golipour, AvroBio, USA
- 15:00 – 15:40 **Plenary Presentation**
Single-cell Multi-omics for accelerated therapeutic characterization and release
Yan Zhang, Mission Bio, USA
- 15:40 – 16:00 **High resolution single cell profiling of human hematopoietic stem cell drug products**
Luca Biasco, AvroBio, USA
- 16:00 – 16:20 **Scientific solutions for regulatory guidelines: Unlocking AAV product testing**
Stuart Wright, Sartorius, United Kingdom
- 16:20 – 16:40 **Platform approaches to mRNA analytical testing methods**
Amy Glekas, MilliporeSigma, USA
- 16:40 – 17:00 **Q&A Panel**
- 17:00 – 17:45 Coffee Break (***Sponsored by Passage Bio***)
- 17:45 – 18:05 **Applying new technology and approaches to the analytical challenge of assessing the empty full ratio for adeno associated virus**
Ian Anderson, Pharmaron, United Kingdom
- 18:05 – 18:25 **Development of a disruptive mass photometry technology for AAV empty full quantification**
Maria Barreira, Cell and Gene Therapy Catapult, United Kingdom
- 18:25 – 18:45 **Quality implications of cryopreservation: Building a small-scale model to determine the shelf-life of cryopreserved blood products for drug product manufacturing**
Purna Venkataraman, Bluebird Bio, USA
- 18:45 – 19:05 **Q&A Panel**
- 19:30 – 21:30 Conference Banquet (Pavilion)

Thursday, February 10, 2022

- 07:00 – 08:30 Bites for Breakfast & Departure

Poster Presentations

Gene Editing and Non-viral Gene Delivery

1. **Manufacturing of gene-modified human mesenchymal stromal cells in microcarriers and agitated conditions**
Pedro Silva Couto, University College London, United Kingdom
2. **Virus-Free CRISPR CAR T cells induce solid tumor regression**
Lauren Sarko, University of Wisconsin, USA

Advances in Viral Vector Manufacturing

3. **Process optimization for adenovirus-based viral vector vaccines**
Syed Khalil, Thermo Fisher Scientific, USA
4. **The role of NIIMBL to advance manufacturing for Cell and Gene Therapy treatments**
Barry Buckland, NIIMBL, USA
5. **An efficient microcarrier based Adeno-associated virus production method**
Brian Ladd, KTH, Royal Institute of Technology, Sweden
6. **Process development of a serum-free and scalable lentiviral vector manufacturing platform for cellular immunotherapies.**
Carme Ripoll Fiol, University College London, United Kingdom
7. **Expression of anti-apoptotic genes to enhance rAAV production**
David Catalán-Tatjer, Technical University of Denmark, Denmark
8. **Enhancing rAAV production by HEK293 cells via metabolic profiling**
Michela Pulix, University of Manchester, United Kingdom
9. **Downstream Improvement for Recombinant Adeno-Associated Viruses (rAAV) Produced in iCELLis Nano 4 m2 Adherent Bioreactor**
Paromita Majumder, Pall Corporation, United Kingdom
10. **Production of a fusogenic oncolytic rVSV-NDV virus: Cell-line screening and process development in small-scale suspension cultures**
Sven Göbel, Max-Planck Institute, Germany
11. **WITHDRAWN**
12. **Continuous production of lentiviral vectors using a fixed-bed bioreactor**
Dale Stibbs, University College London, United Kingdom
13. **WITHDRAWN**
14. **Scaling viral vector production processes into HyPerforma DynaDrive Single-Use Bioreactors**
Paula Decaria, Thermo Fisher Scientific, USA
15. **Intensification of viral vector production and clarification by integration of perfusion platforms**
Rene Gantier, Repligen, USA

Advances in Cell Therapy Manufacturing

16. **Impact of intermediate volumes and cell diameters on cell recovery: A predictive model for autologous immunotherapy workflows**
Craig Mizzoni, Cytiva, USA
17. **Developing an effective scale-down model for a suspension adapted Hek293t-derived lentiviral vector stable producer cell line**
Hamza Patel, University College London, United Kingdom
18. **Viability enrichment of final drug product using counter-flow centrifugation**
Jonathan Lim, Bristol Myers Squibb, USA
19. **Development of cGMP manufacturing processes for the large-scale production of cell-based therapies for commercial applications**
Krishna M. Panchalingam, Lonza, USA
20. **High-throughput affinity-resin based scale down method for T cell isolation**
Marielle Summers, Bristol Myers Squibb, USA
21. **Challenges and solutions for allogeneic cell therapy manufacturing**
Sunghoon Jung, PBS Biotech, Inc., USA
22. **Towards an integrated bioprocess for scalable production and isolation of MSC-derived extracellular vesicles for cardiac repair**
Marta Costa, iBET, ITQB-NOVA, Portugal
23. **Developmental lineage of human pluripotent stem cell-derived cardiac fibroblast affects their functional phenotype**
Martha Floy, University of Wisconsin-Madison, USA
24. **Computational fluid dynamic characterization of vertical-wheel bioreactors used for effective scale-up of human induced pluripotent stem cell aggregate culture**
Breanna Borys, University of Calgary, Canada
25. **Protocol development to overcome bioprocess bottlenecks in the large-scale expansion of high quality hiPSC aggregates in vertical-wheel bioreactors**
Breanna Borys, University of Calgary, Canada
26. **Virtual reality to rapidly scale a resilient workforce for cell and gene therapy manufacturing**
Ivan Wall, FourPlus Immersive & National Training Centre for Advanced Therapies Manufacturing, United Kingdom
27. **Induced pluripotent stem cells for candidate cell line selection of off-the-shelf natural killer cell therapy**
Jason Mills, CenturyTx, USA
28. **A nature-inspired protocol to generate mature hiPSC-derived hepatocytes: Unveiling the role of human intestinal microbiome**
Joana I. Almeida, iBET, ITQB, Portugal
29. **Bioprocess optimization for generation of hepatocytes derived from hiPSC and its application in primary hyperoxaluria type 1 disease modelling**
Joana I. Almeida, iBET, ITQB, Portugal

30. **Manufacturing of patient specific novel T cell therapies using the Cocoon® Platform automated system**
Joseph O'Connor, Lonza, USA
31. **Erbi Biosystems - Cell culture development with a 2 mL continuous perfusion bioreactor**
Kevin Lee, Erbi Biosystems Inc., USA
32. **A scalable bioreactor for the expansion of anchorage-dependent stem cells**
Nicholas McMahon, Southwest Research Institute, USA
33. **Proof-of-concept of a novel scalable magnetic bead-based cell separation technology**
Nils Brechmann, KTH, Royal Institute of Technology, Sweden
34. **hiPSC and hiPSC-cardiomyocytes are alternative EV biofactories for cardiac regeneration**
Paula Marques Alves, iBET, ITQB, Portugal
35. **Deterministic cell processing recovers >2-fold more cells, and up to 5-fold more naïve T cells, as compared to centrifugally prepared cells**
Tony Ward, GPB Scientific, USA
36. **Process development and scale-up for gene circuit engineered CAR-NK cell manufacturing**
Travis Wood, Senti Bio, USA

Analytics and Big Data

37. **Systems-level discovery of quality attributes and candidate pathways for optimized production of human pluripotent stem cell-derived cardiomyocytes**
Aaron Simmons, University of Wisconsin, USA
38. **Development of analytical assays for the characterization of gene circuit enabled cell therapies**
Brett Kiedaisch, Senti Biosciences, USA
39. **Transitioning cell-based processes towards scalable production**
Isabelle Espiritu, ViaCyte, Inc, USA
40. **Process development for improved Car-t production utilizing an automated perfusion stirred-tank bioreactor**
Tiffany Hood, University College London, United Kingdom

The Future of Product Release

41. **Rapid product characterization for release using membrane microscopy**
Adam Ross, Halo Labs, USA