UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**FORM 8-K**

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 24, 2015

**ASSEMBLY BIOSCIENCES, INC.**
(Exact name of registrant as specified in its charter)

| Delaware | 001-35005 | 20-8729264 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer ID Number) |

| 99 Hudson Street, 5th Floor, New York, New York | 10013 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code (646) 706-5208

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 2.02. Results of Operations and Financial Condition.**

Assembly Biosciences, Inc. expects that its cash and cash equivalents at December 31, 2014 will be approximately $29.0 million.

**Item 8.01. Other Events.**

Attached hereto as Exhibit 99.1 is a company presentation that Assembly Biosciences, Inc. will use for various investor presentations and which is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Company presentation of February 2015. |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**ASSEMBLY BIOSCIENCES, INC.**

Date: February 24, 2015

/s/ David J. Barrett
David J. Barrett, Chief Financial Officer

**Exhibit 99.1**


Assembly Biosciences
February 2015
assembly
biosciences

# Forward-Looking Statements

This presentation contains forward-looking statements regarding future events. Forward-looking statements involve known and unknown risks that could cause actual results to differ materially from expected results. These risks and uncertainties include, among others: risks related to the scientific bases, costs, timing, regulatory review and results of our studies and clinical trials; our ability to obtain FDA and other regulatory approval of our product candidates; our anticipated capital expenditures, our estimates regarding our capital requirements, and our need for future capital; the unpredictability of the size of the markets for, and market acceptance of, any of our product candidates; our ability to sell any approved products and the price we are able to realize; our ability to obtain future funding on acceptable terms; our ability to retain and hire necessary employees and to staff our operations appropriately; our ability to compete in our industry and innovation by our competitors; our ability to stay abreast of and comply with new or modified laws and regulations that currently apply or become applicable to our business; and the risks set out in our filings with the SEC.

# Assembly Biosciences – Overview

*Building a world class infectious disease company*

**Two Proprietary Technology Platforms, Best-In-Class Science and Novel Drugs for HBV and CDAD**

## HBV Platform

- **Multiple differentiated mechanisms and molecules**
- Core Protein Allosteric Modifiers (CpAMs):
  - Multiple differentiated products in pipeline
- Enables combination or mono therapies of unique mechanisms to increase cure rates

## Microbiome Platform

- ***C. Difficile*** **(CDAD)**
- Targeted, Oral Delivery of synthetic Microbiome Therapeutics
- 1st disease focus, CDAD infections
- Expected in clinic in 2016; pipeline following

***All current programs discovered and developed in-house***

# Assembly Biosciences - Organization

*Thought leadership in infectious disease and specifically HBV experience*

**Derek A. Small – Pres, CEO** - Founding CEO of multiple biotechs

**David Barrett – COO & CFO -** CFO, director at multiple biotechs

**Uri Lopatin, MD – CMO, VP R&D** - Led HBV programs at leading bio/pharma

**Lee Arnold, PhD – CSO** – Discoverer of Tarceva® and >7 other candidates

**Adam Zlotnick, PhD – SAB Chair (HBV)** – Science founder, professor at IU

**Russell Ellison, MD – Head of Microbiome –** Multiple other drugs on market

## Board of Directors

**William R. Ringo – Chairman** – Lilly, Abgenix, Intermune, Pfizer, Onyx

**Tony Altig** – Maxim Pharma, Optimer, Derversia, others

**Mark Auerbach** – RCS, Par Pharma, Optimer, others

**Richard DiMarchi, PhD** – Lilly, Indiana Univ, Ambrx, Marcadia, Collibrium

**Myron Holubiak** – Roche, BioScript, Intellicell, Leonard+Meron

## Assembly's HBV-Cure Research Group

***Discovery and Development In House and With Key Collaborations***

*Chemistry – Biochemistry – Biology*
*Novel Target Research*

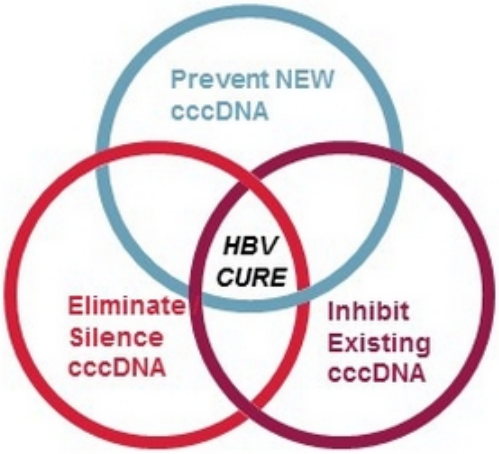
*San Francisco, CA – Bloomington, IN*

*Collaborators: Several HBV researchers globally*

***Proven track record of innovation with deep science***
***Team has collectively discovered >20 clinical candidates & >10 marketed drugs***

# Our Approach to an HBV Cure

**Our Approach: Leverage HBc to Target cccDNA**

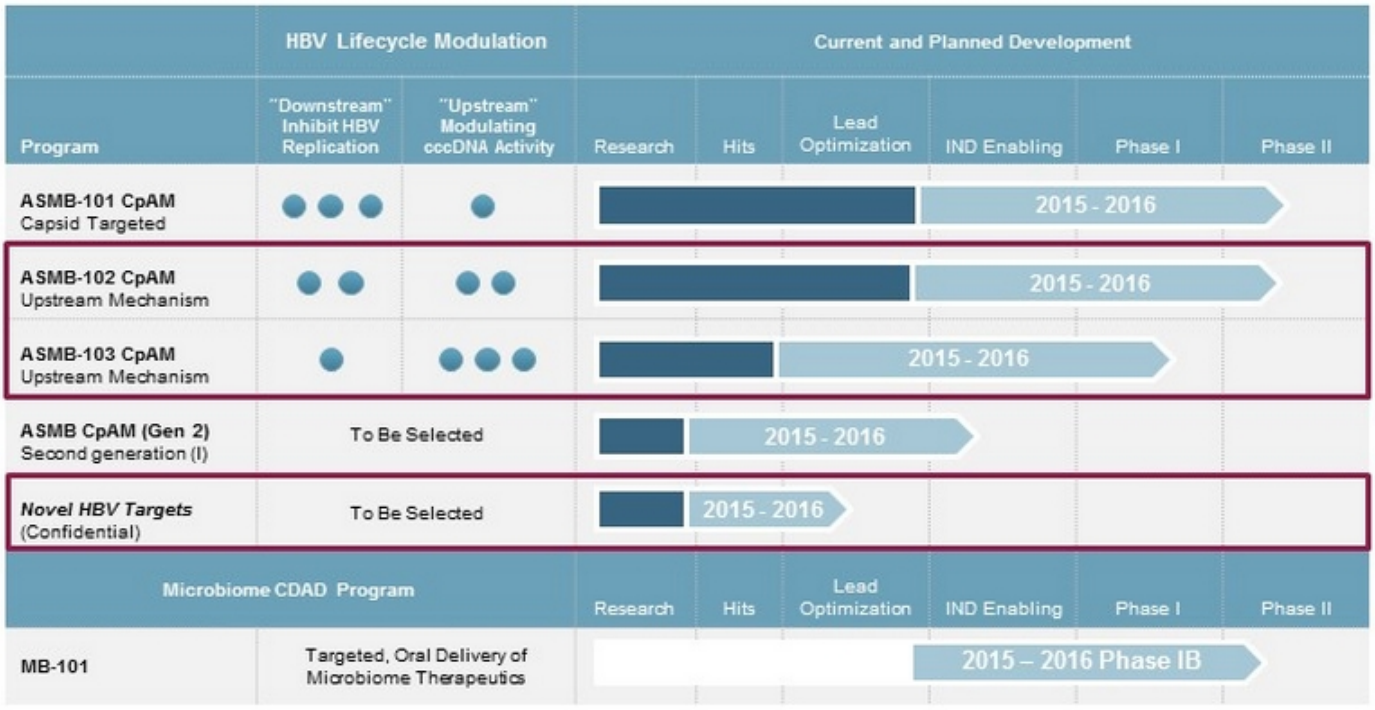



**Our Core Competencies and Competitive Advantage**

HBV Biology | Proprietary Enabling Assays | World Class Chemistry | Clinical Expertise

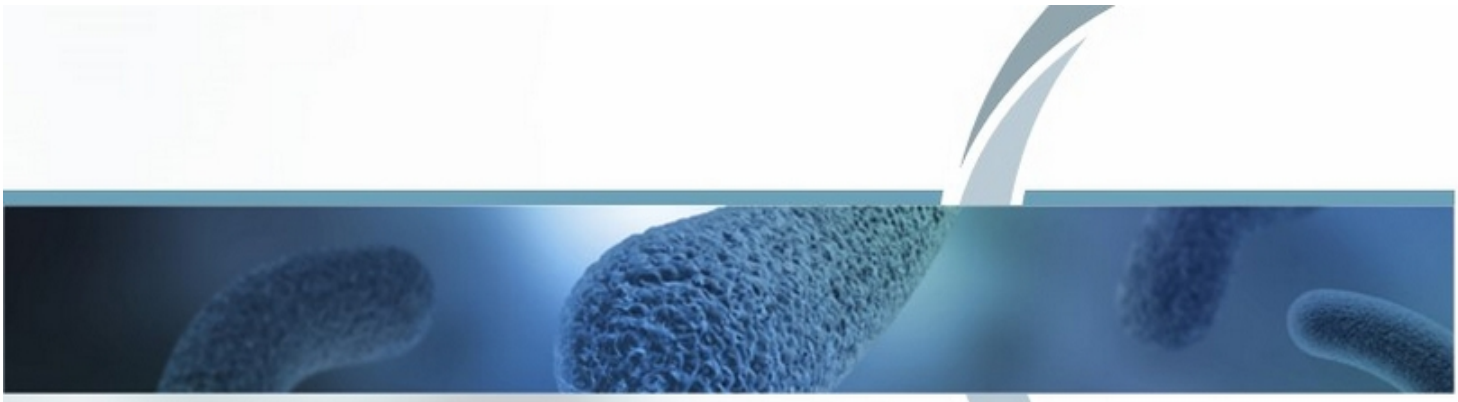
Intellectual Property

# Pipeline Progress – Building Momentum




Newly Announced Programs

- Rights to all molecules and platforms are owned by and exclusive to Assembly

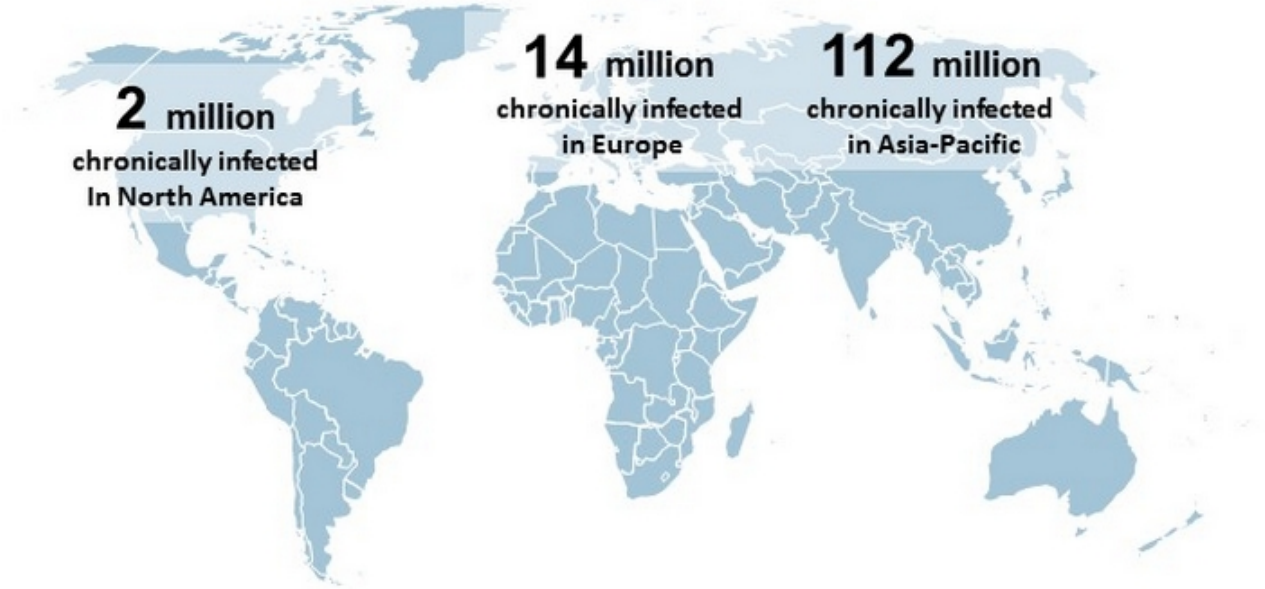


# HBV Background & Assembly Approach

assembly biosciences

# HBV Global Unmet Medical Need

- >350 million people worldwide have chronic hepatitis B infection
- 10-30M new patients each year & **>600K deaths/year**




***WW sales of $3.2B in 2012 with only ~5% of chronic patients treated***

Source: WHO, Ferlay et al. Globocan (2002), Ministry of Health of the People's Republic of China, Ulmer, T et al. (2007) and CDC.

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1. **HBV is a DNA virus – unlike HCV, HBV viral reservoir (cccDNA) is in the nucleus**
2. **Curative therapy for HBV will require modulation and destabilization or silencing of cccDNA**
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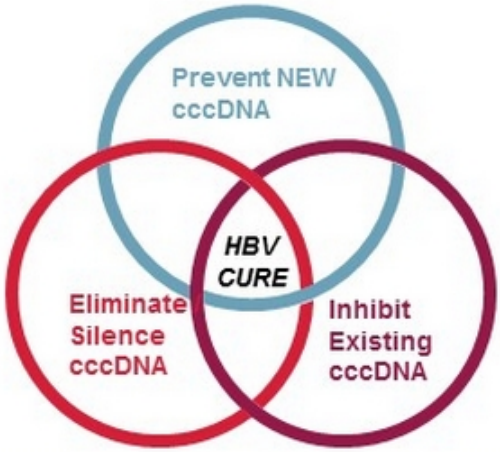


***Our goal is to develop small molecule oral therapies to sustainably suppress or eliminate cccDNA by leveraging our expertise in HBV Core Protein***

(1) New therapeutic targets and drugs for the treatment of chronic hepatitis B. Seimars in Liv Dis **33**, 130–137 (2013).
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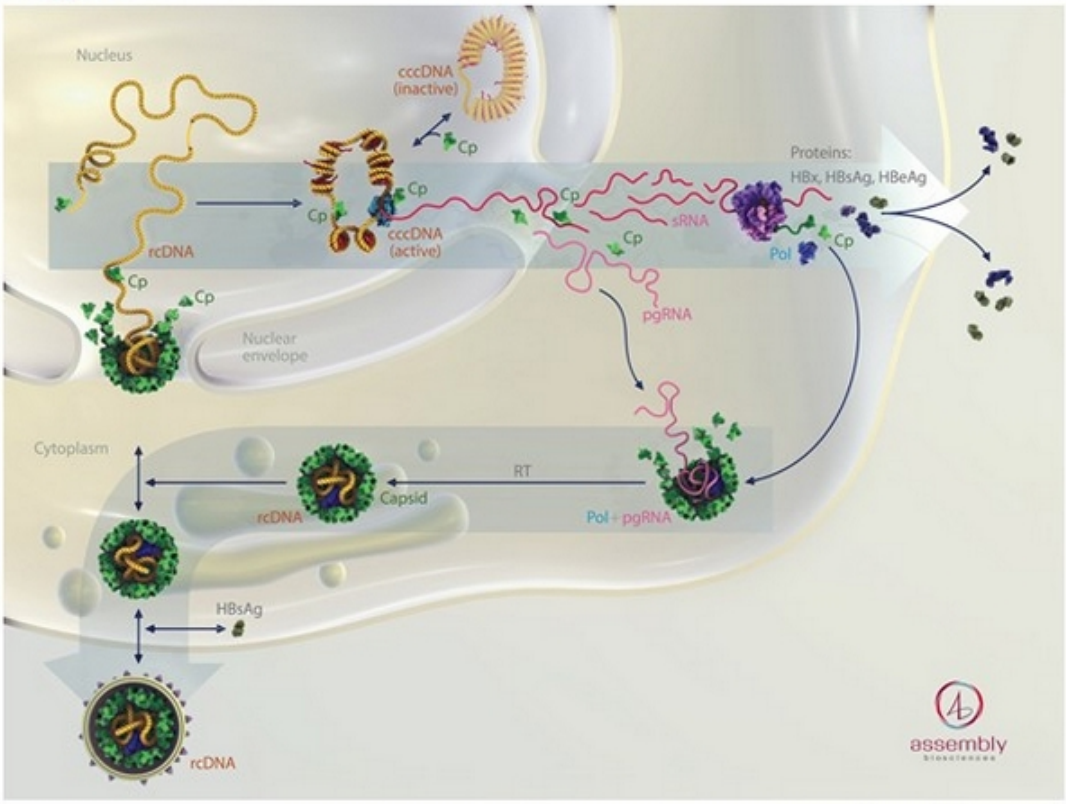
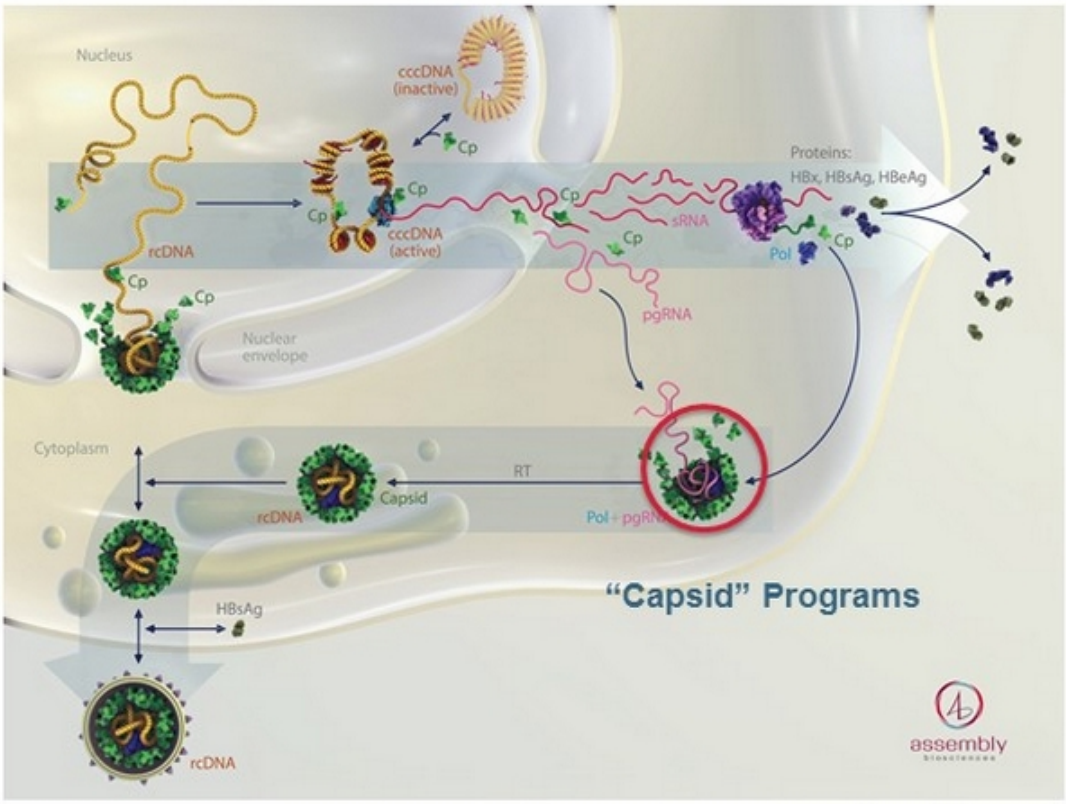
# HBV Lifecycle

*HBV is a DNA virus unlike HCV; Core Protein is involved in all aspects of the viral lifecycle*



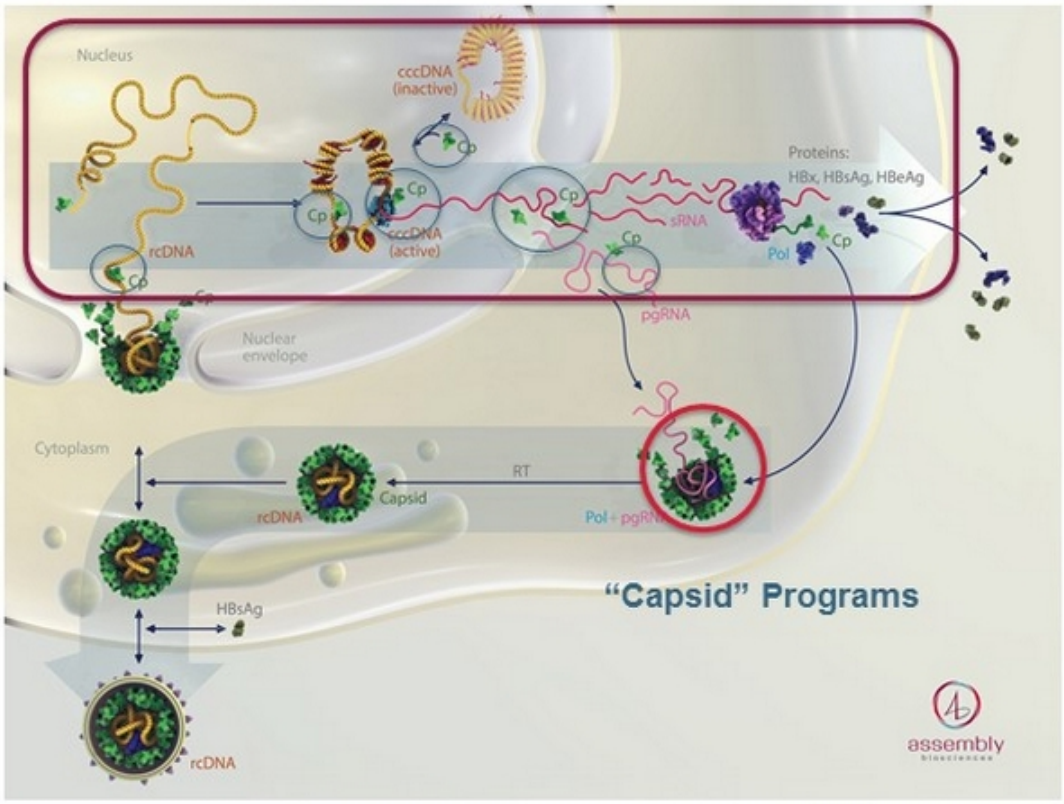
# Capsid Programs Target Downstream

*Downstream therapies are unlikely to be curative as monotherapy*



# Assembly's Core Protein Programs

*Assembly's CpAMs target upstream and downstream in the viral lifecycle*



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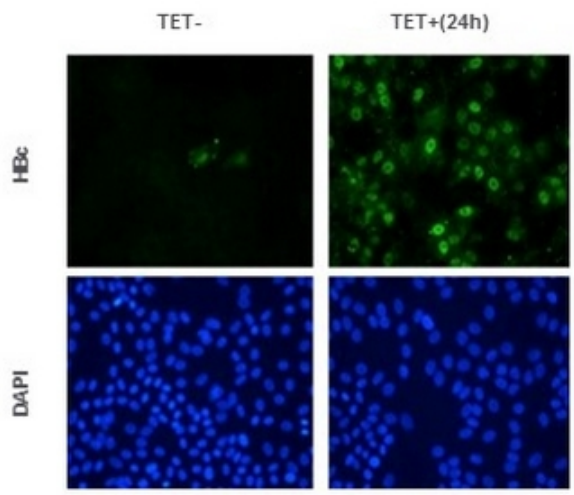
# Program and Pipeline Overview

## Core Protein Rationale

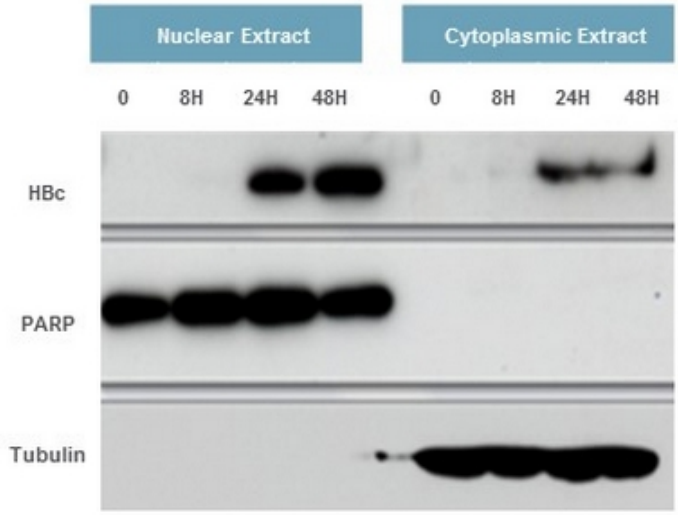
# Core Protein Localizes to the Nucleus of Infected Cells

*Preclinical data (Cell culture)*

**Sub-cellular Localization of HBc Protein in HBc Expressing Cell Line (HepaRG-TR-HBc)**




HepaRG-TR-HBc (If anti-HBc)



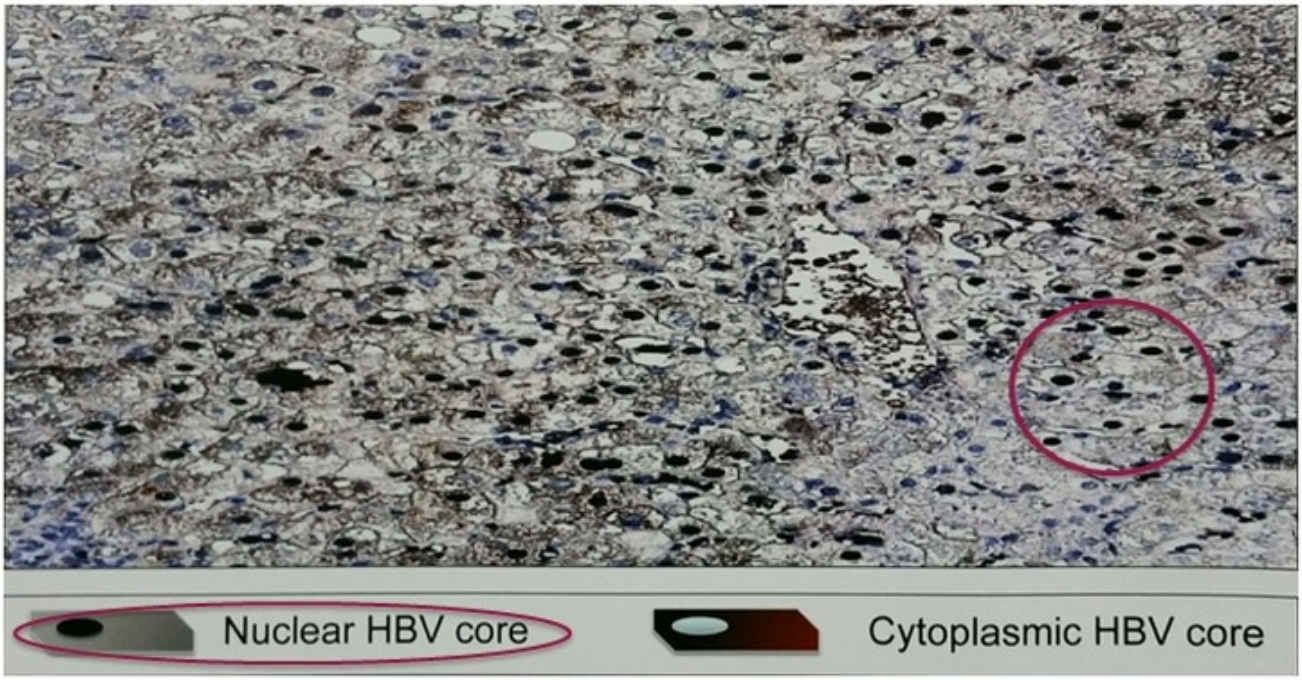

HepaRG-TR-HBc (WB)

***HBV core protein is mostly localized in the nucleus***

Source: Durantel et al. AASLD. Presented at EASL.

# Core Protein Localizes to the Nucleus of Patient Cells

Representative **clinical data**: Histopathology of HBeAg +, High viral load patient




Courtesy Patrick Kennedy MD

# Core Protein has MULTIPLE Roles Modulating cccDNA

## HBc Regulates cccDNA Expression

Epigenetics 6:6, 720-726; June 2011; © 2011 Landes Bioscience

**HBc binds to the CpG islands of HBV cccDNA and promotes an epigenetic permissive state**

## HBc Regulates cccDNA Persistence

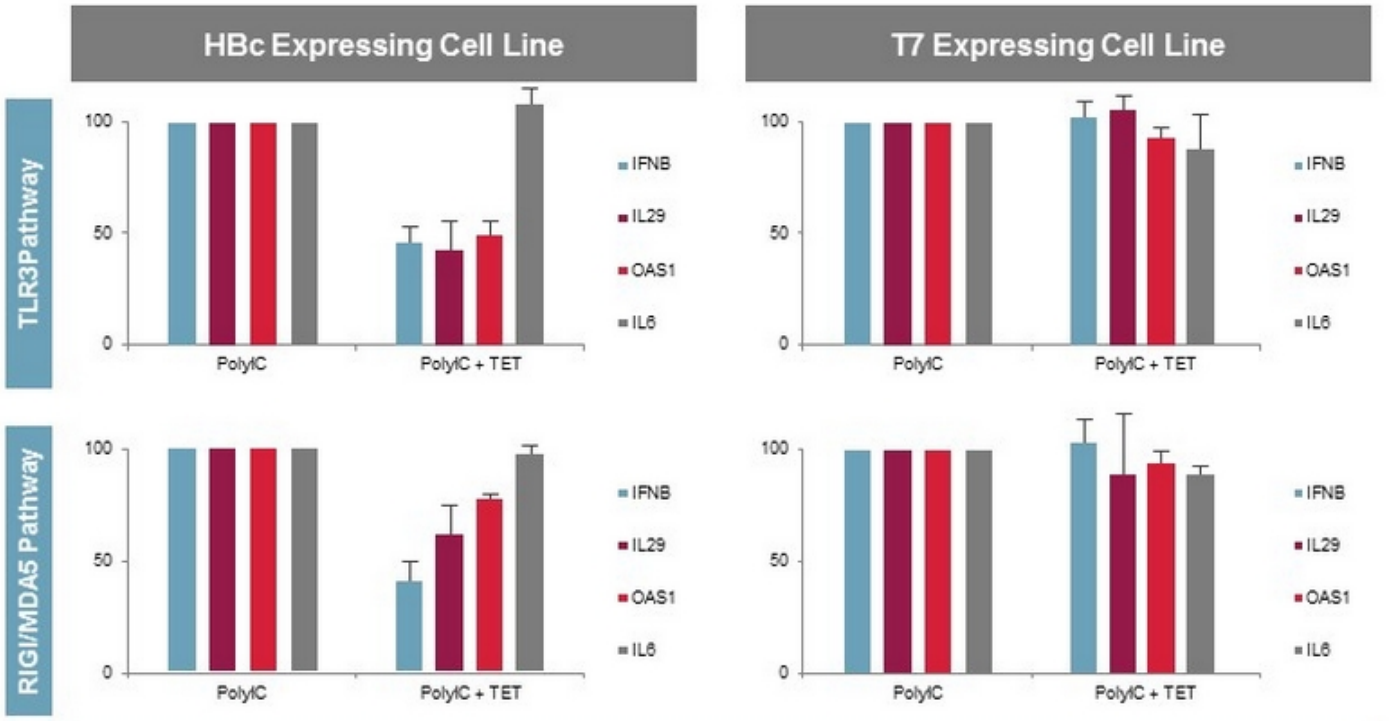
Science. 2014 Mar 14;343(6176):1221-8. doi: 10.1126/science.1243462. Epub 2014 Feb 20.

**Specific and nonhepatotoxic degradation of nuclear hepatitis B virus cccDNA.**

Lucifora J[1], Xia Y, Reisinger F, Zhang K, Stadler D, Cheng X, Sprinzl MF, Koppensteiner H, Makowska Z, Volz T, Remouchamps C, Chou WM, Thasler WE, Hüser N, Durantel D, Liang TJ, Münk C, Heim MH, Browning JL, Dejardin E, Dandri M, Schindler M, Heikenwalder M, Protzer U.

# HBc Modulates Immune Response

*HBc expression interferes with hepatocyte innate response*

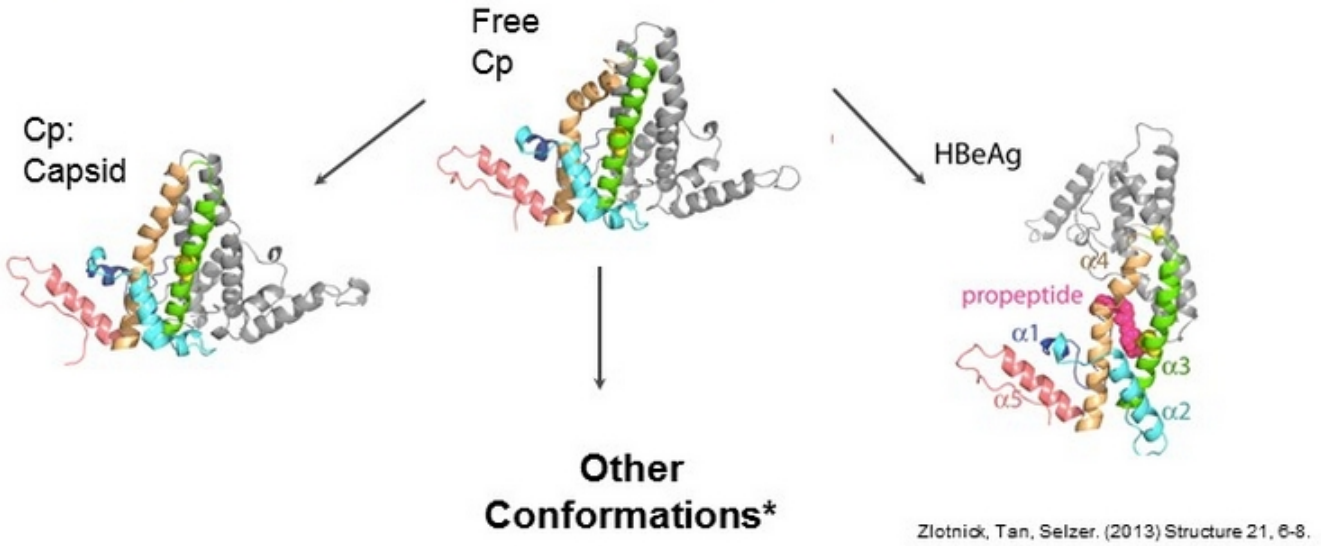



***Inhibition of IFN response (type I/III) and associated ISGs independently of the pathway engaged***
***No inhibition of the proinflammatory pathway (IL-6) by HBc***

Source: Durantel et al. AASLD. Presented at EASL.

# Core Protein Provides ASMB *Multiple* Targets

*HBV core protein has multiple functions and conformations*




Zlotnick, Tan, Selzer. (2013) Structure 21, 6-8.

***Assembly has a best in class team to understand core protein. Targeting Core PLEOTROPIC core functions by allosteric modulation of Cp conformation is a differentiating advantage of Assembly***

# HBV-Cure Pipeline – Clinical Strategy

| Program | HBV Lifecycle Modulation | | Current and Planned Development | | | | | |
|---|---|---|---|---|---|---|---|---|
| | "Downstream" Inhibit HBV Replication | "Upstream" Modulating cccDNA Activity | Research | Hits | Lead Optimization | IND Enabling | Phase I | Phase II |
| **ASMB-101 CpAM** Capsid Targeted | ●●● | ● | | | | 2015 - 2016 | | |
| **ASMB-102 CpAM** Upstream Mechanism | ●● | ●● | | | | 2015 - 2016 | | |
| **ASMB-103 CpAM** Upstream Mechanism | ● | ●●● | | | | 2015 - 2016 | | |
| **ASMB CpAM (Gen 2)** Second generation (I) | To Be Selected | | | | 2015 - 2016 | | | |
| ***Novel HBV Targets*** (Confidential) | To Be Selected | | | | 2015 - 2016 | | | |

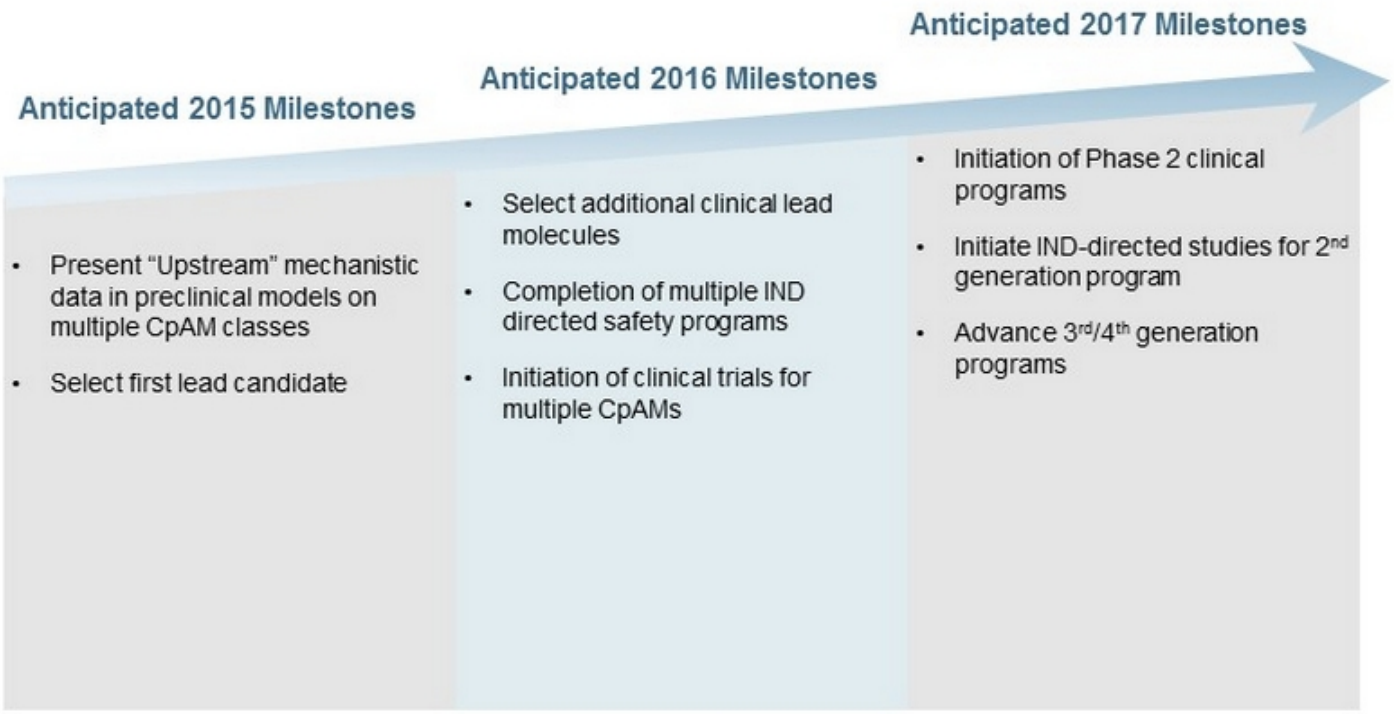
## Clinical Strategy – CpAM Monotherapy and Combinations

CpAMs classes show efficacy as monotherapy. Multiple classes allows exploration of CpAMs in combination across CpAM classes AND with other classes of HBV therapy.

Planned clinical program:

- Phase I (safety) studies as single agents
- Phase IB studies in patients as single agents and in combination with nucleos(t)ides polymerase inhibitors
- Phase II studies will explore duration of therapy in dose finding single agent and combination studies (across CpAM classes and with other classes of therapy)
- Phase III studies will be based on Phase II results

# HBV Program Milestones



# Intellectual Property Portfolio: HBV & CpAMs

**The patent applications fall broadly into two categories:**

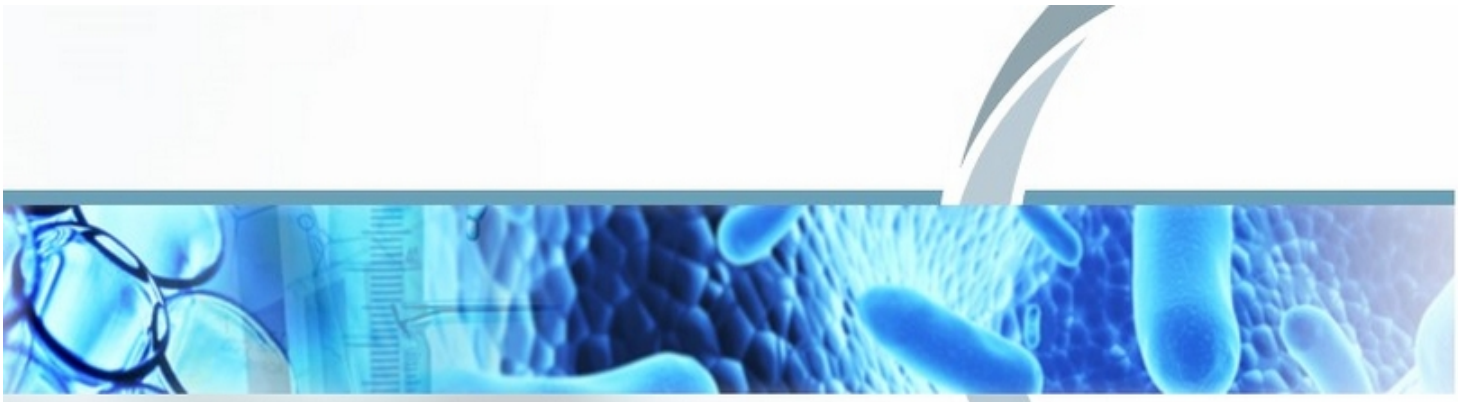
**1. Platform patent applications – Core Protein**

- Multiple platform patent applications filed, with others in process
- Patent applications cover novel mechanism of action, methods of treatment, novel assays, and other aspects of novel HBV Core Protein mechanisms

**2. Composition of matter patent applications – Novel CpAMs**

- Several compound, structure, and composition of matter applications pending

***We have a portfolio of filings to date, and expect to be filing more***
***Our patent portfolio is intended to cover significant geography in HBV***



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# Microbiome Program: *C. Difficile*

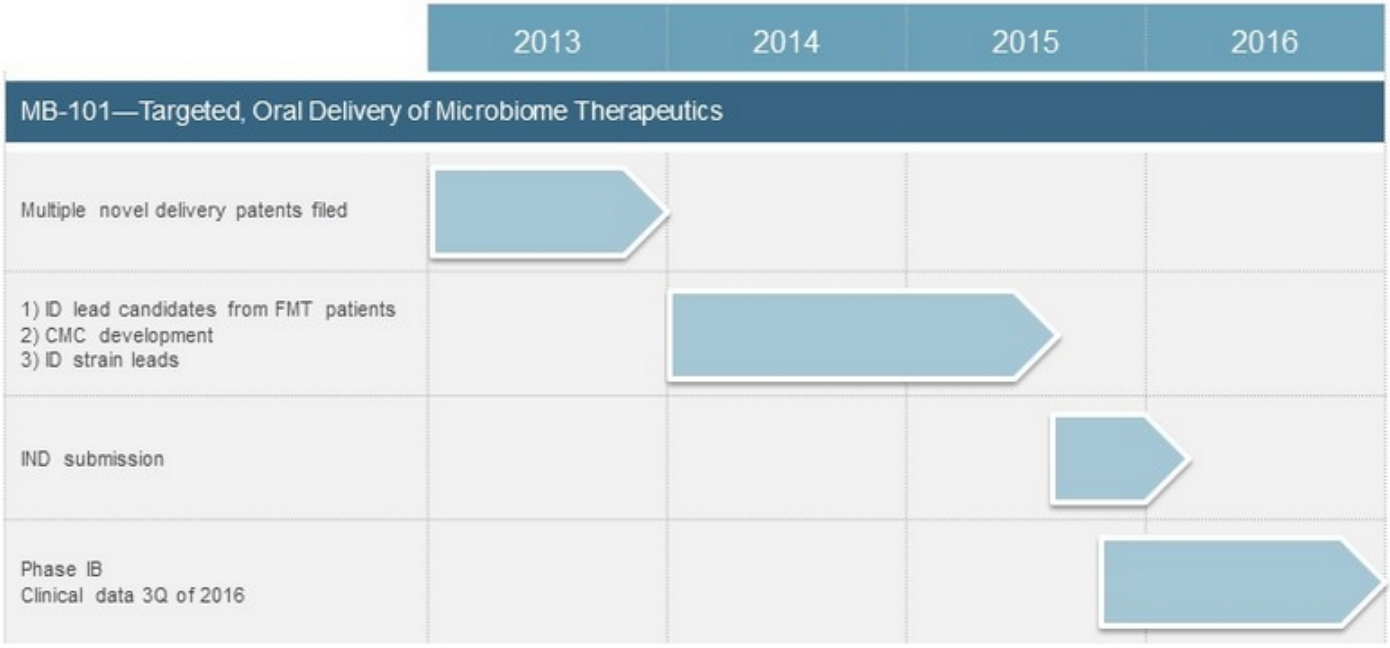
# Microbiome Therapeutics: Overview

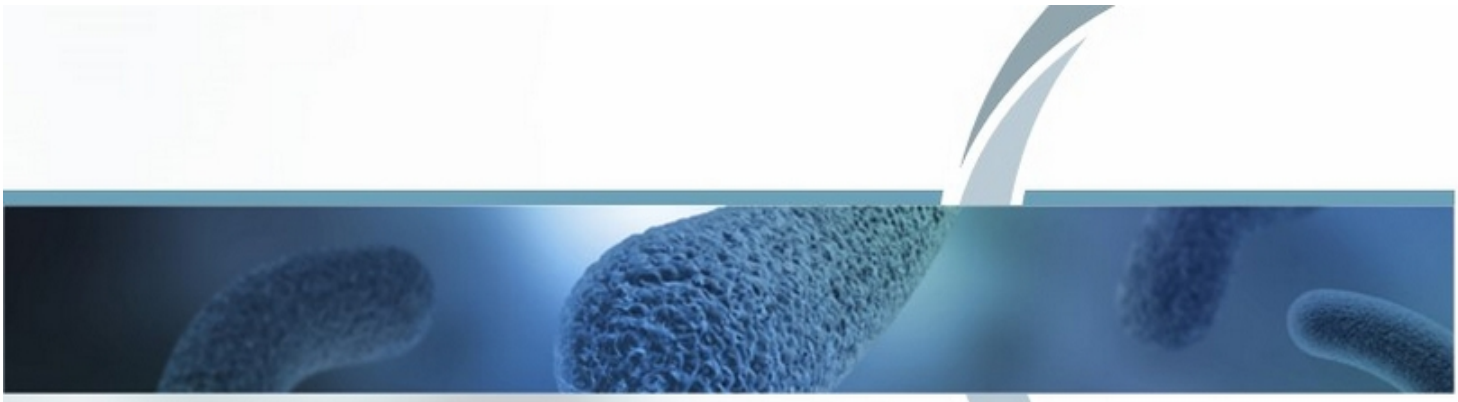
- We have in-licensed technology for targeted delivery of complex agents to select regions of the GI tract
- Our delivery technology utilizes state of the art encapsulation technology and new coating technologies in conjunction to exploit specific pH gradients across the gut.
  - This is designed to deliver complex agents to the proximal colon and / or terminal ileum
- ***C. Difficile*** infection provides an excellent path for proof of concept of microbiome therapy approach
  - ***C. Difficile*** is a recognized major health problem and increasing in incidence
  - FMT has provided the most clear success in therapy to date: Durable cure within 24hrs
  - Success reported with minimal mixtures of bacterial strains

***Assembly's approach: Selected strains (GMP product) delivered in an oral-capsule based therapy to recapitulate cure rates seen in FMT***

# Microbiome Therapeutics: Overview (cont'd)

## *Microbiome CDAD Program – Planned Development*





# Financials & Key Investment Highlights

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# Financial Summary

| | |
|---|---|
| Ticker | **Nasdaq: ASMB** |
| Cash & Cash Equivalents | **~$29M as of Dec 2014** |
| Shares Outstanding | **~10.6M (insiders own 3M, institutional investors own 4.6M)** |
| Fully Diluted Shares Outstanding | **~13.8M** |
| Highlights | • **ASMB merger July 2014**<br>• **Capital raise of $15.8M in October 2014** (max under baby shelf at that time)<br>• **$120M shelf S-3 filing in December 2014 provides flexibility to opportunistically access the capital markets** (Full shelf now accessible) |

# Investment Highlights

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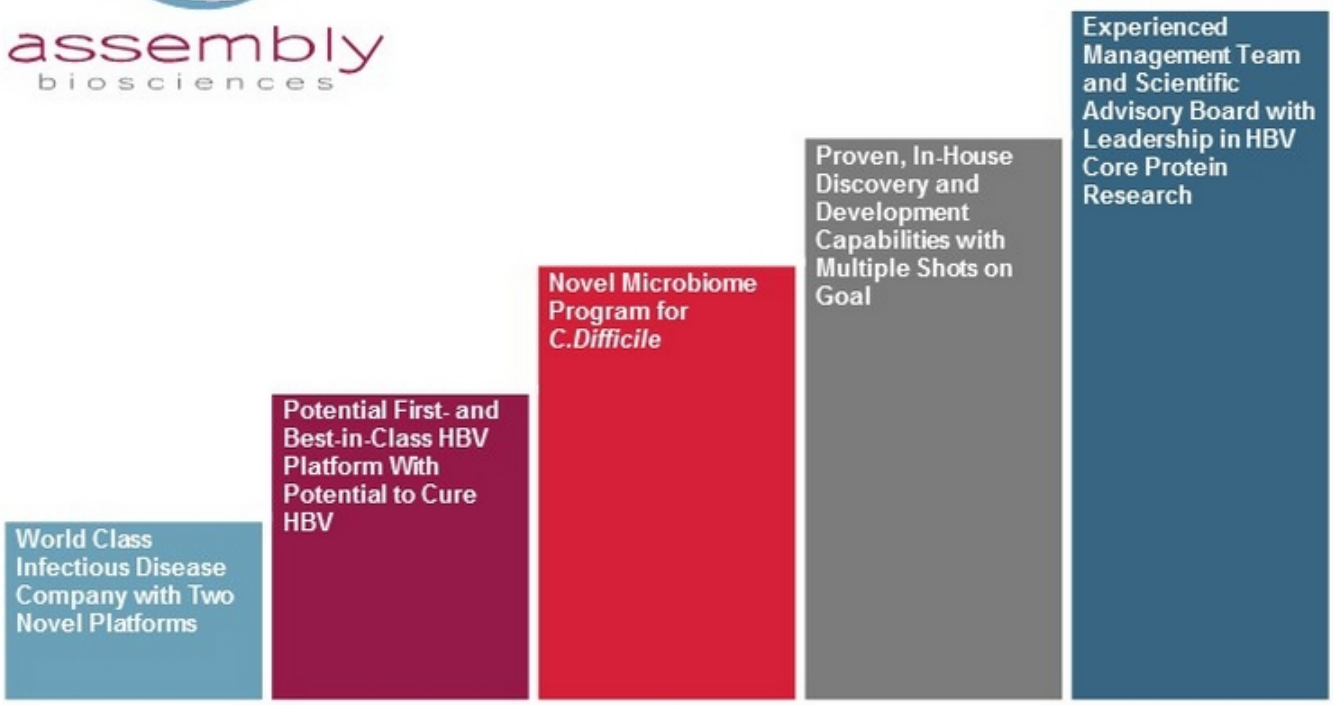


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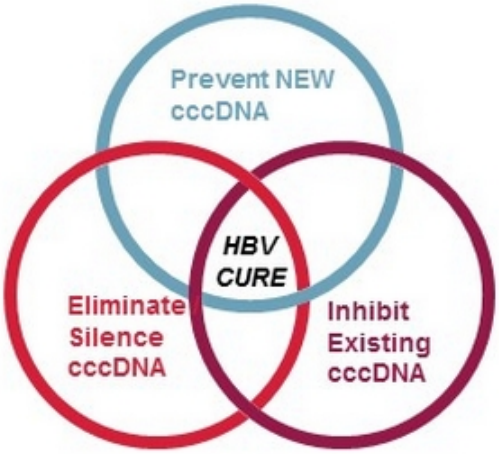


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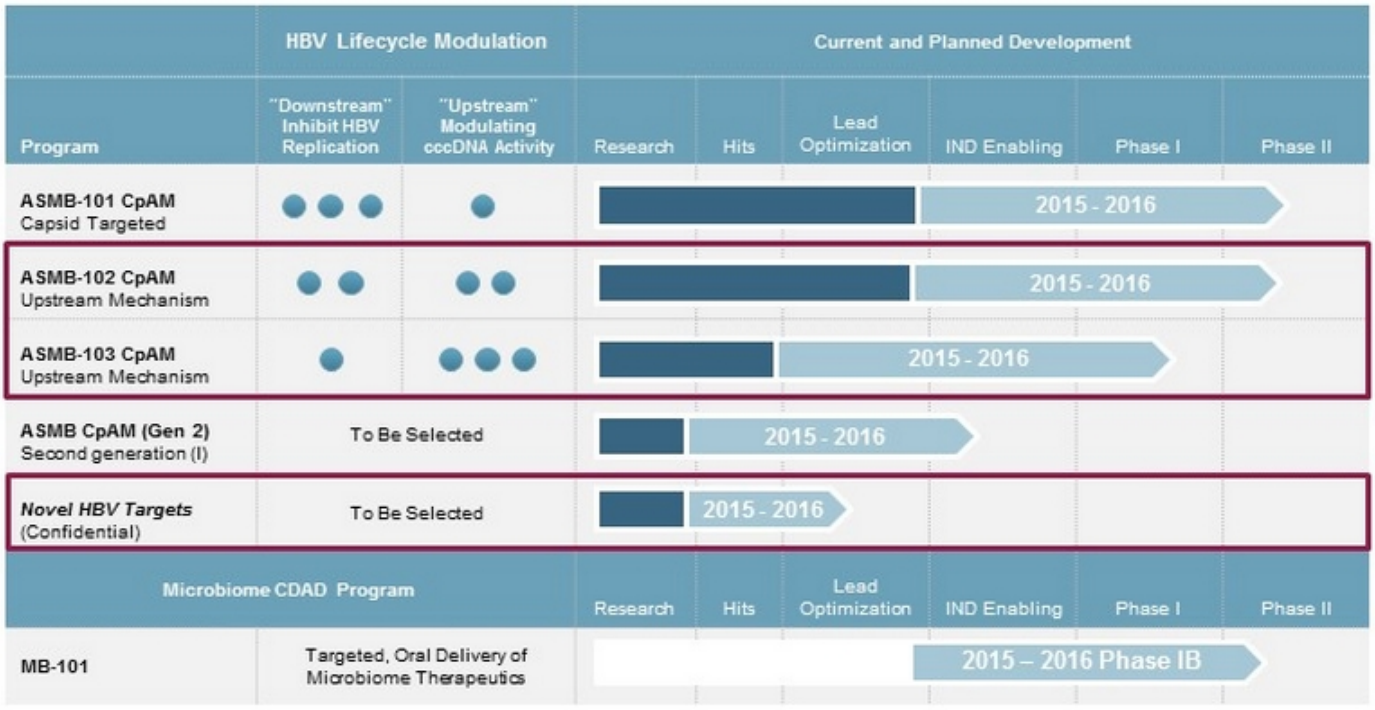


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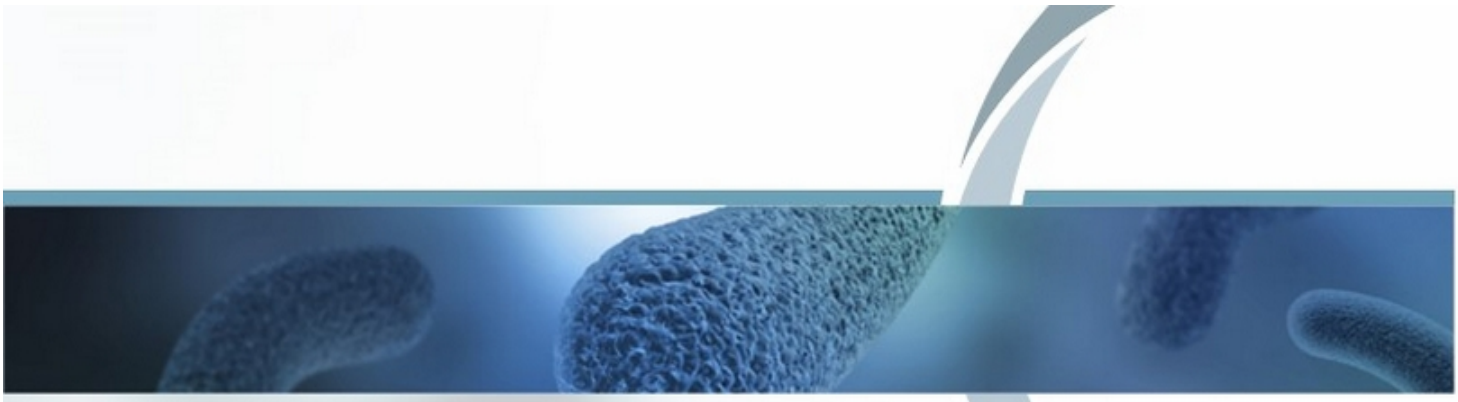

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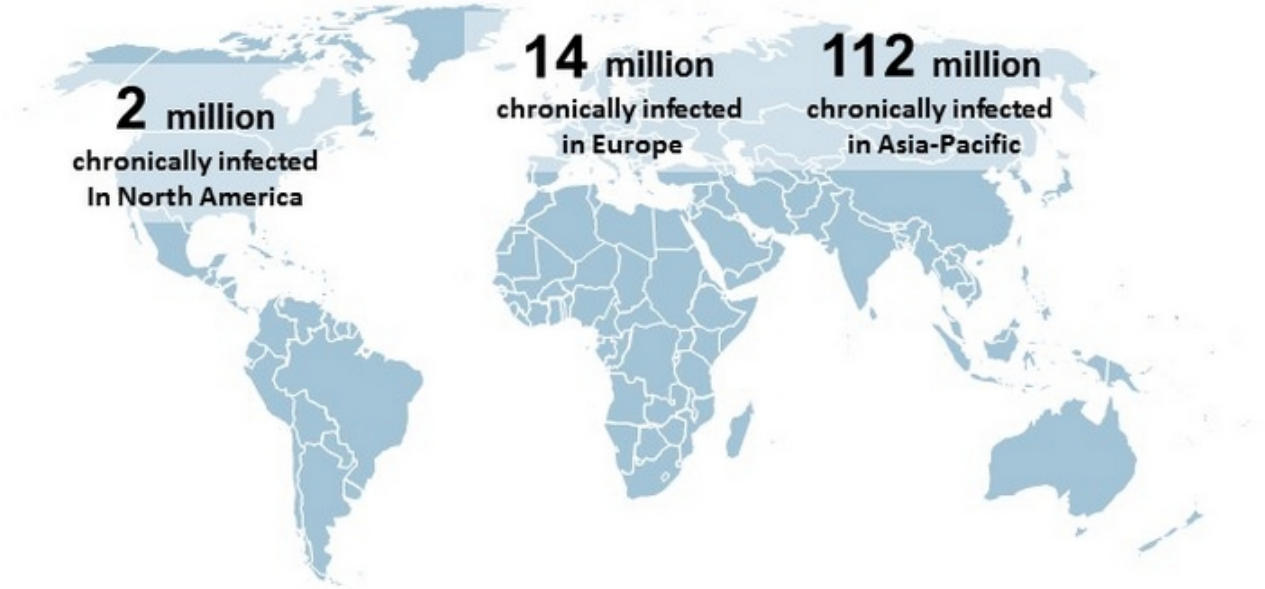


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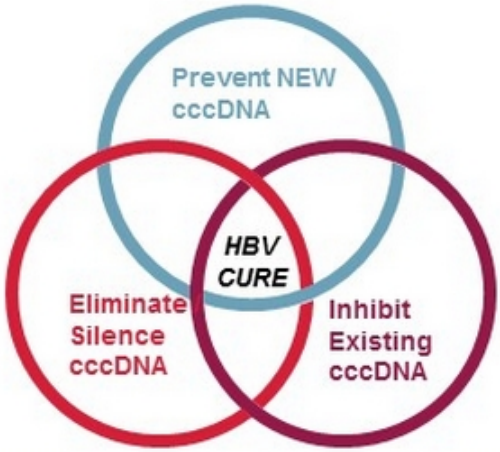


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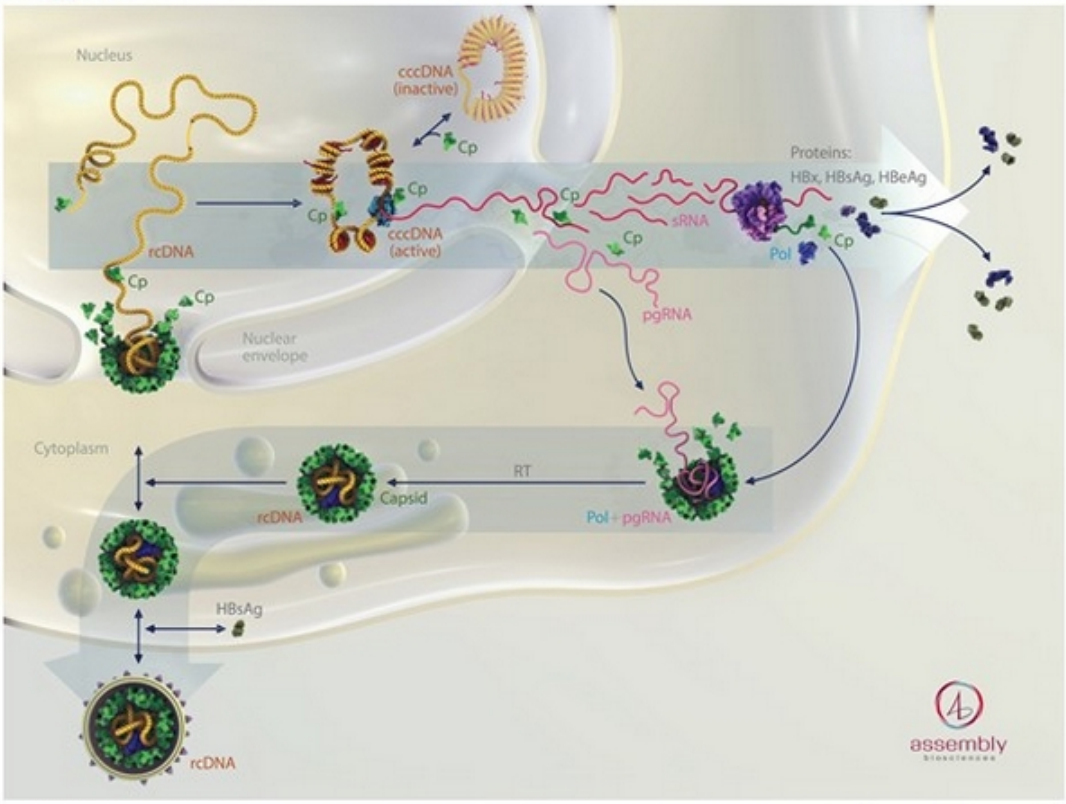

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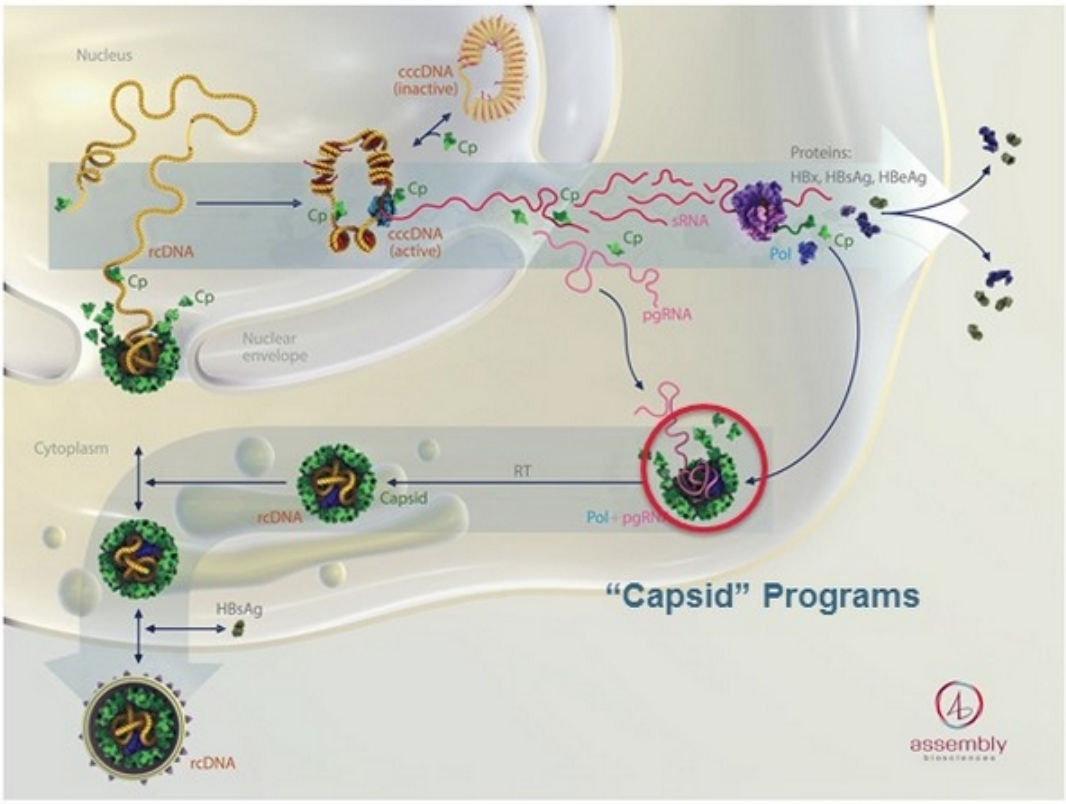
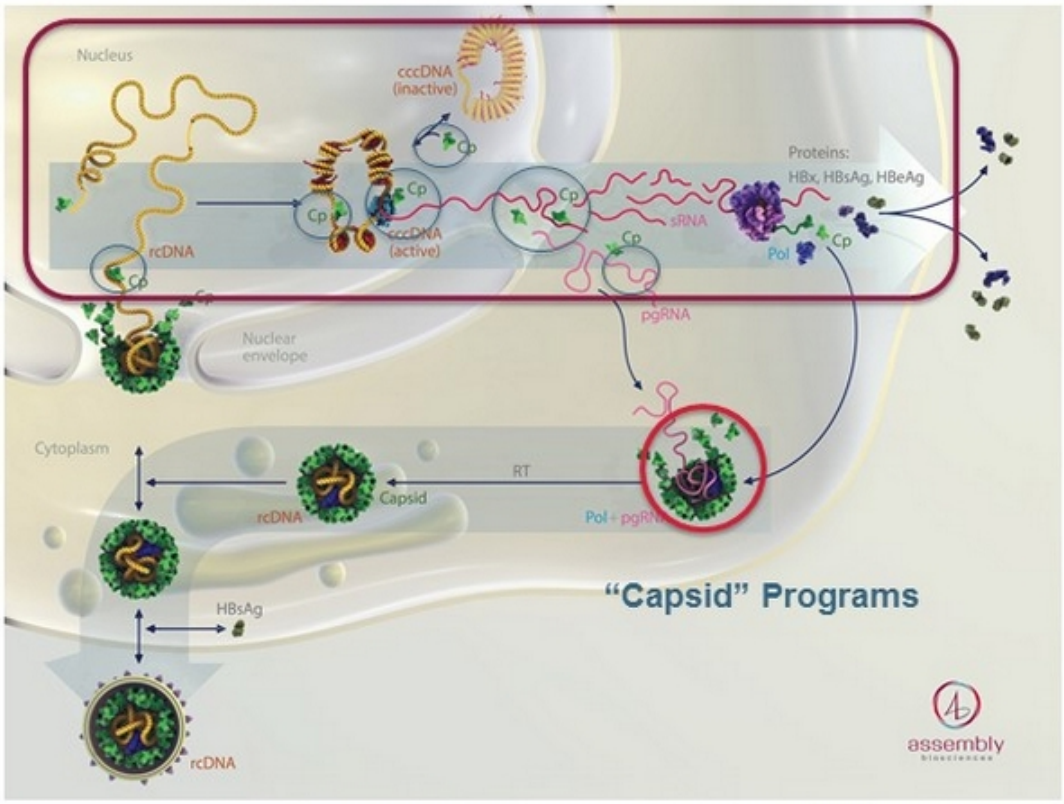


# Assembly's Core Protein Programs

*Assembly's CpAMs target upstream and downstream in the viral lifecycle*



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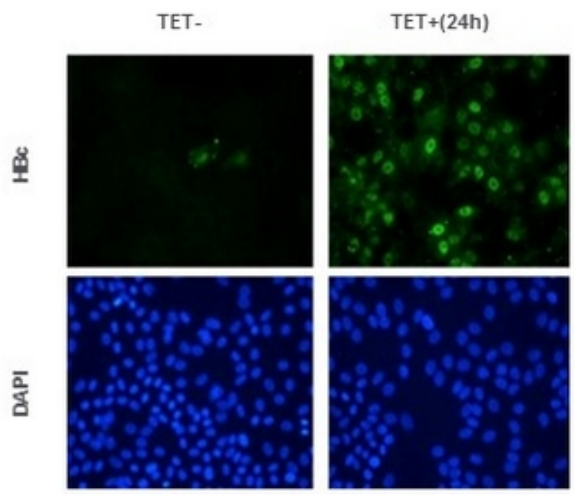
# Program and Pipeline Overview

## Core Protein Rationale

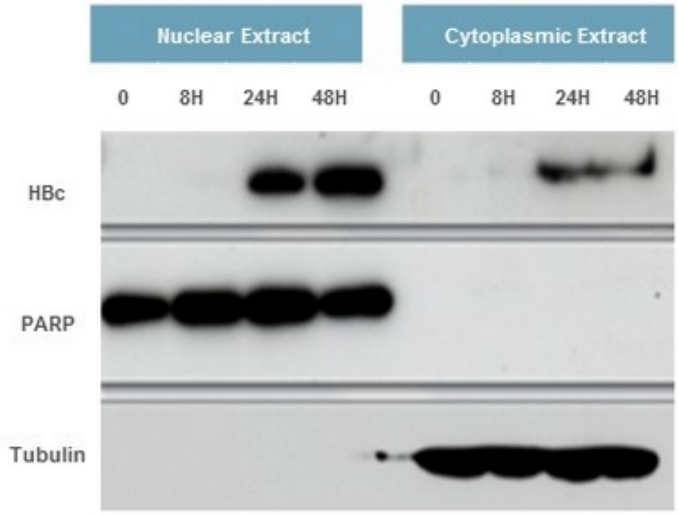
# Core Protein Localizes to the Nucleus of Infected Cells

*Preclinical data (Cell culture)*

**Sub-cellular Localization of HBc Protein in HBc Expressing Cell Line (HepaRG-TR-HBc)**




HepaRG-TR-HBc (If anti-HBc)



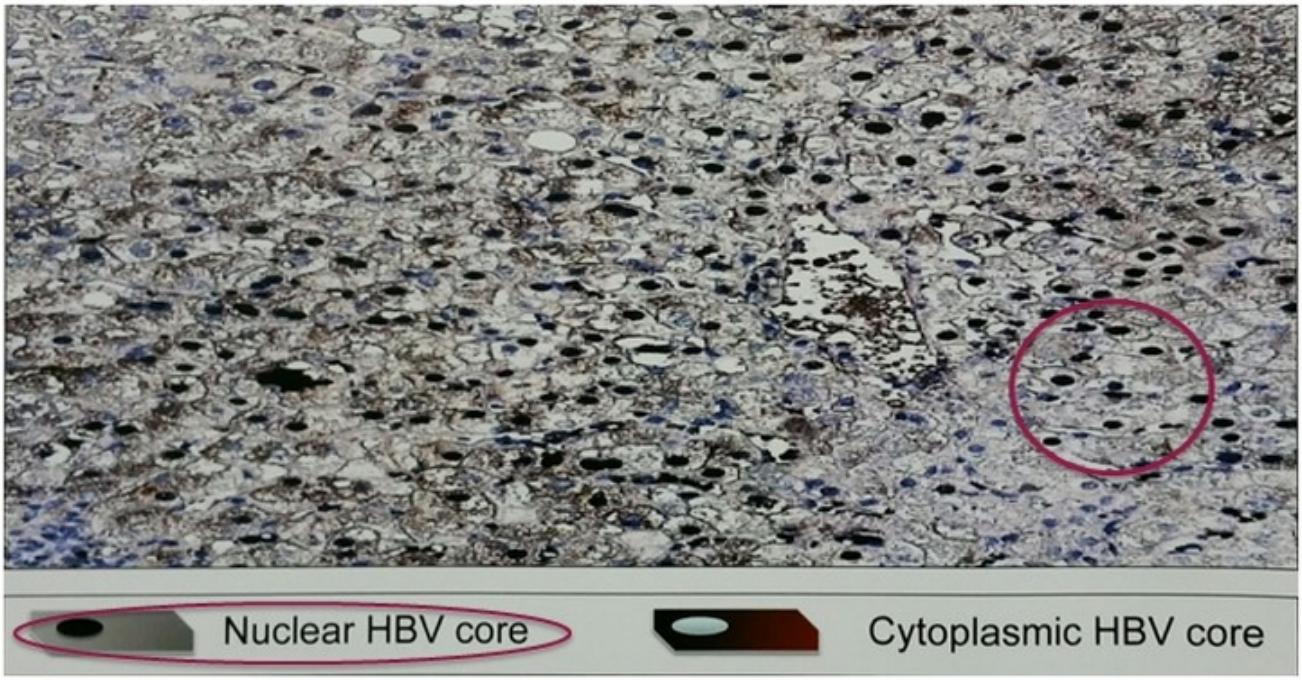

HepaRG-TR-HBc (WB)

***HBV core protein is mostly localized in the nucleus***

Source: Durantel et al. AASLD. Presented at EASL.

# Core Protein Localizes to the Nucleus of Patient Cells

Representative **clinical data**: Histopathology of HBeAg +, High viral load patient




Courtesy Patrick Kennedy MD

# Core Protein has MULTIPLE Roles Modulating cccDNA

## HBc Regulates cccDNA Expression

Epigenetics 6:6, 720-726; June 2011; © 2011 Landes Bioscience

**HBc binds to the CpG islands of HBV cccDNA and promotes an epigenetic permissive state**

## HBc Regulates cccDNA Persistence

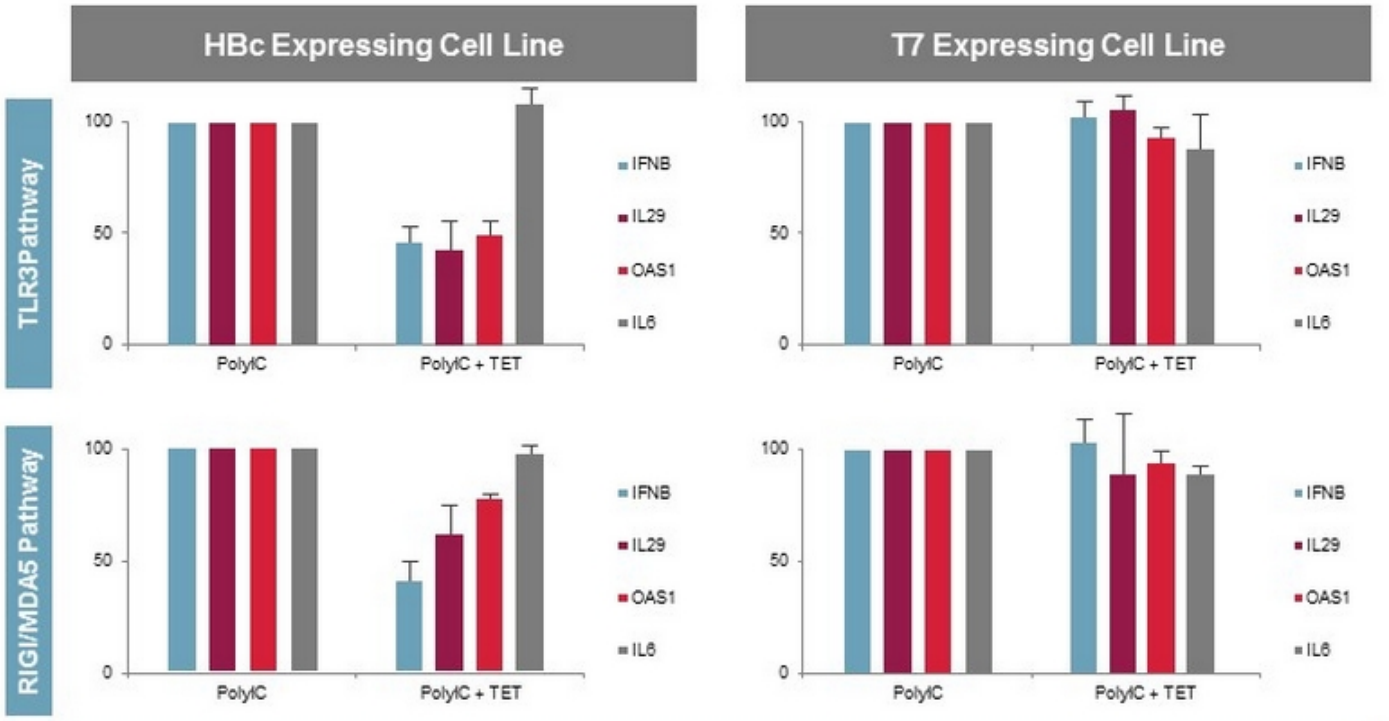
Science. 2014 Mar 14;343(6176):1221-8. doi: 10.1126/science.1243462. Epub 2014 Feb 20.

**Specific and nonhepatotoxic degradation of nuclear hepatitis B virus cccDNA.**

Lucifora J[1], Xia Y, Reisinger F, Zhang K, Stadler D, Cheng X, Sprinzl MF, Koppensteiner H, Makowska Z, Volz T, Remouchamps C, Chou WM, Thasler WE, Hüser N, Durantel D, Liang TJ, Münk C, Heim MH, Browning JL, Dejardin E, Dandri M, Schindler M, Heikenwalder M, Protzer U.

# HBc Modulates Immune Response

*HBc expression interferes with hepatocyte innate response*

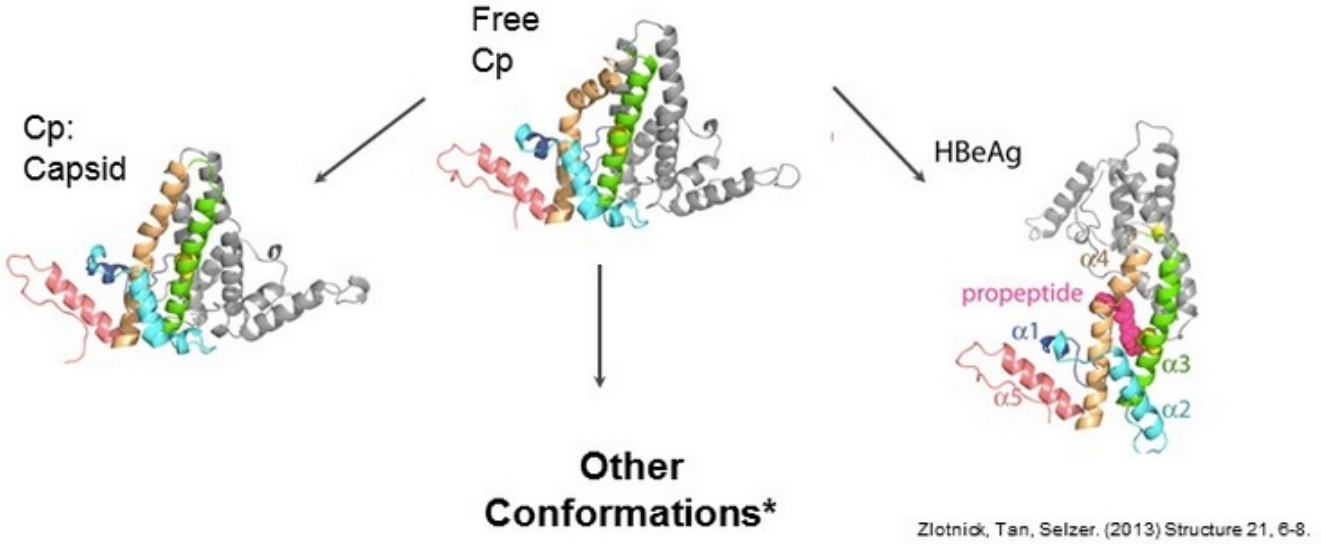



***Inhibition of IFN response (type I/III) and associated ISGs independently of the pathway engaged***
***No inhibition of the proinflammatory pathway (IL-6) by HBc***

Source: Durantel et al. AASLD. Presented at EASL.

# Core Protein Provides ASMB *Multiple* Targets

*HBV core protein has multiple functions and conformations*




Zlotnick, Tan, Selzer. (2013) Structure 21, 6-8.

***Assembly has a best in class team to understand core protein. Targeting Core PLEOTROPIC core functions by allosteric modulation of Cp conformation is a differentiating advantage of Assembly***

# HBV-Cure Pipeline – Clinical Strategy

| Program | HBV Lifecycle Modulation: "Downstream" Inhibit HBV Replication | HBV Lifecycle Modulation: "Upstream" Modulating cccDNA Activity | Current and Planned Development |
|---|---|---|---|
| **ASMB-101 CpAM** Capsid Targeted | ● ● ● | ● | 2015 - 2016 |
| **ASMB-102 CpAM** Upstream Mechanism | ● ● | ● ● | 2015 - 2016 |
| **ASMB-103 CpAM** Upstream Mechanism | ● | ● ● ● | 2015 - 2016 |
| **ASMB CpAM (Gen 2)** Second generation (I) | To Be Selected | | 2015 - 2016 |
| ***Novel HBV Targets*** (Confidential) | To Be Selected | | 2015 - 2016 |

Current and Planned Development: Research, Hits, Lead Optimization, IND Enabling, Phase I, Phase II

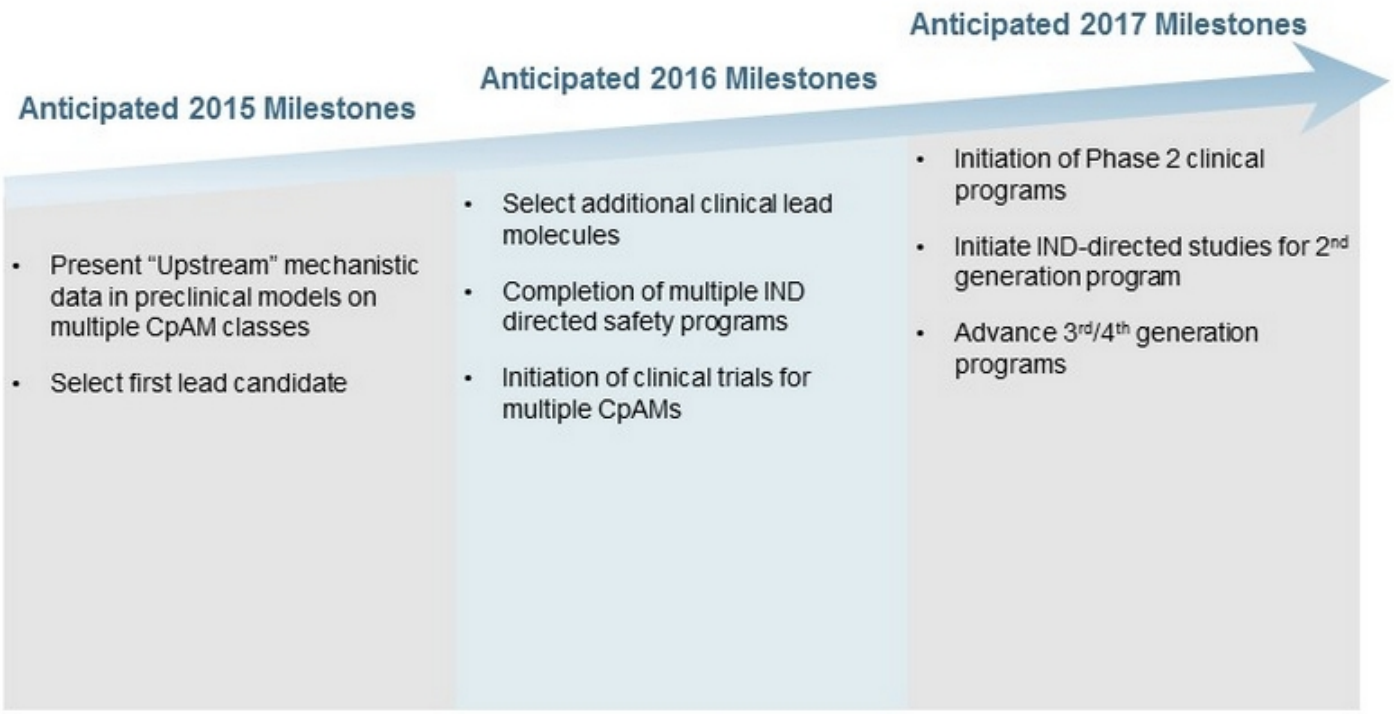
## Clinical Strategy – CpAM Monotherapy and Combinations

CpAMs classes show efficacy as monotherapy. Multiple classes allows exploration of CpAMs in combination across CpAM classes AND with other classes of HBV therapy.

Planned clinical program:

- Phase I (safety) studies as single agents
- Phase IB studies in patients as single agents and in combination with nucleos(t)ides polymerase inhibitors
- Phase II studies will explore duration of therapy in dose finding single agent and combination studies (across CpAM classes and with other classes of therapy)
- Phase III studies will be based on Phase II results

# HBV Program Milestones



# Intellectual Property Portfolio: HBV & CpAMs

**The patent applications fall broadly into two categories:**

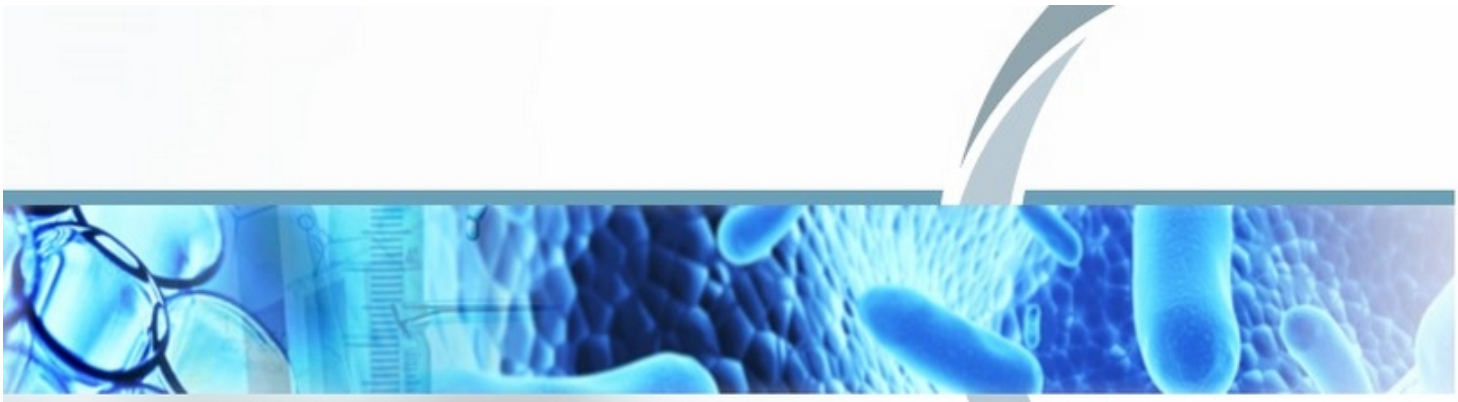
**1. Platform patent applications – Core Protein**

- Multiple platform patent applications filed, with others in process
- Patent applications cover novel mechanism of action, methods of treatment, novel assays, and other aspects of novel HBV Core Protein mechanisms

**2. Composition of matter patent applications – Novel CpAMs**

- Several compound, structure, and composition of matter applications pending

***We have a portfolio of filings to date, and expect to be filing more***
***Our patent portfolio is intended to cover significant geography in HBV***



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# Microbiome Program: *C. Difficile*

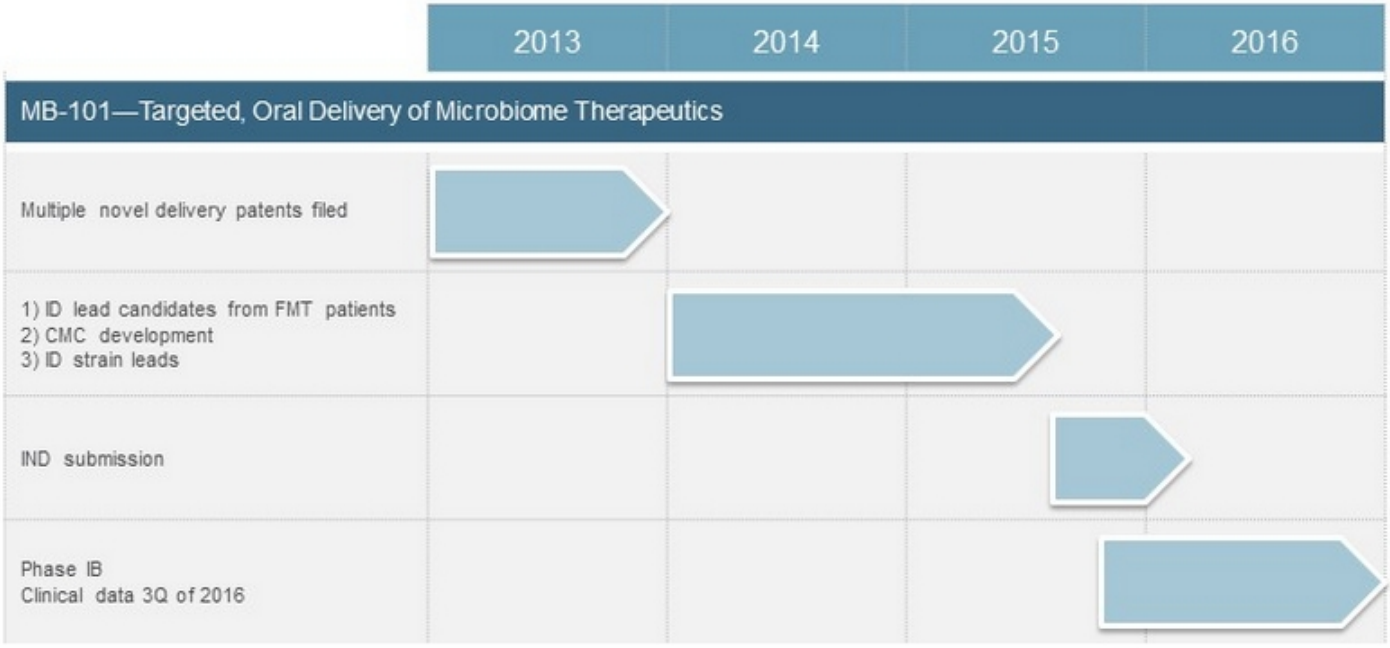
# Microbiome Therapeutics: Overview

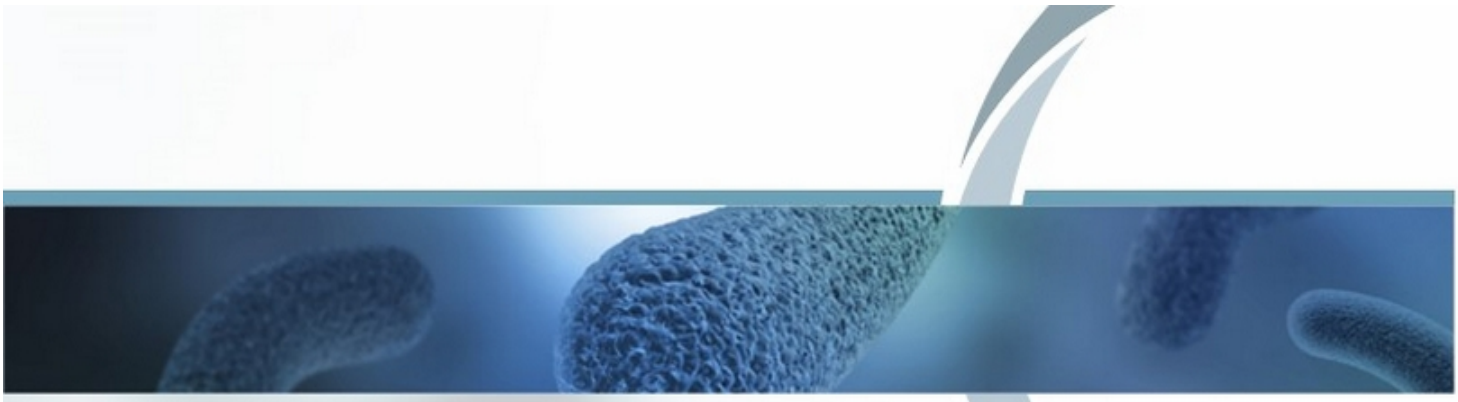
- We have in-licensed technology for targeted delivery of complex agents to select regions of the GI tract
- Our delivery technology utilizes state of the art encapsulation technology and new coating technologies in conjunction to exploit specific pH gradients across the gut.
  - This is designed to deliver complex agents to the proximal colon and / or terminal ileum
- ***C. Difficile*** infection provides an excellent path for proof of concept of microbiome therapy approach
  - ***C. Difficile*** is a recognized major health problem and increasing in incidence
  - FMT has provided the most clear success in therapy to date: Durable cure within 24hrs
  - Success reported with minimal mixtures of bacterial strains

***Assembly's approach: Selected strains (GMP product) delivered in an oral-capsule based therapy to recapitulate cure rates seen in FMT***

# Microbiome Therapeutics: Overview (cont'd)

## *Microbiome CDAD Program – Planned Development*





# Financials & Key Investment Highlights

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# Financial Summary

| | |
|---|---|
| Ticker | **Nasdaq: ASMB** |
| Cash & Cash Equivalents | **~$29M as of Dec 2014** |
| Shares Outstanding | **~10.6M (insiders own 3M, institutional investors own 4.6M)** |
| Fully Diluted Shares Outstanding | **~13.8M** |
| Highlights | • **ASMB merger July 2014**<br>• **Capital raise of $15.8M in October 2014** (max under baby shelf at that time)<br>• **$120M shelf S-3 filing in December 2014 provides flexibility to opportunistically access the capital markets** (Full shelf now accessible) |

# Investment Highlights