

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): August 13, 2014

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 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Company presentation of August 2014.

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: August 13, 2014

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



*Assembly Biosciences
August 2014*



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 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



Infectious Disease Focused → Potential Curative Therapy for Hepatitis B and *Clostridium difficile*

Two Proprietary Technology Platforms

- **Core Protein Allosteric Modifiers (CpAMs)** – 1st focus, HBV
- **Targeted Delivery of Microbiome Therapeutics** – 1st focus, *C. difficile*

Pipeline Offers First-in-class and/or Best-in-class Product Opportunities

- **HBV: 1st Gen** Molecule expected in clinic by early 2016; **2nd Gen** following
- **CDAD: 1st Gen** Microbiome therapeutic expected in clinic by early 2016; pipeline following

Experienced Management and R&D Team

Russell Ellison, MD – CEO, Chair – Pegasys and multiple other drugs on market

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

David Barrett – CFO – CFO; director at multiple biotechs

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

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

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



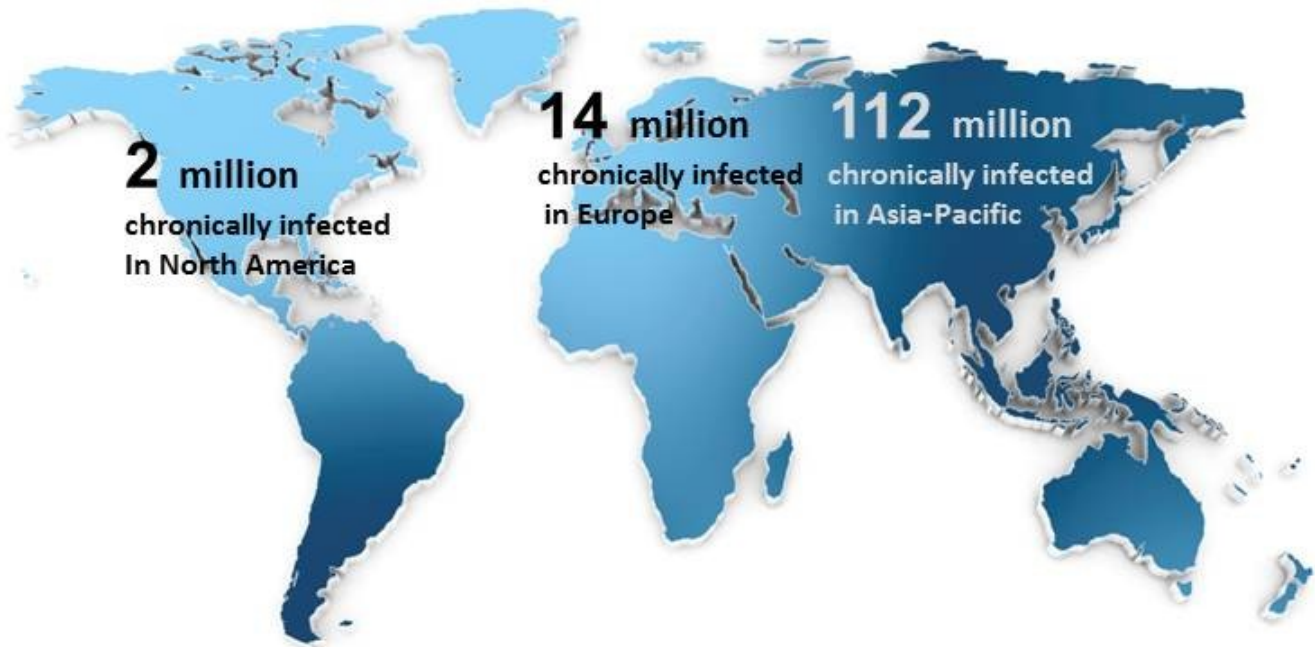
Why HBV?



HBV by the Numbers



More than 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; most patients remain untreated or untreatable

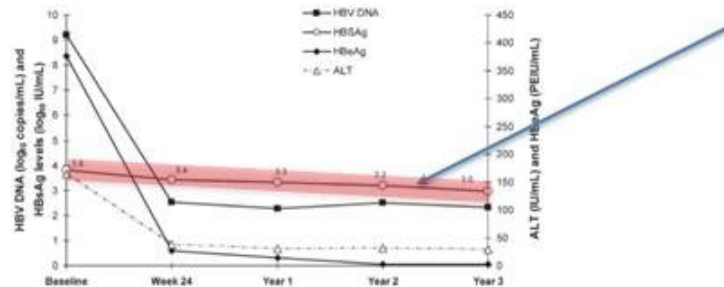
Piper Jaffray est. \$15B/yr. W/W
RBC est. \$10B/yr.+ W/W

HBV is Both Underdiagnosed and Undertreated



- **Current Therapy Suppresses Virus, but Does Not Cure**

3 Year Decline
in HBsAg*



- **Lack of curative therapy** contributes to under diagnosis and under treatment**
- **Finite therapy should increase treated patient populations**
 - More patients willing/able to be diagnosed
 - More patients willing/able to be treated
 - More physicians willing to initiate treatment

* Wursthorn, K. *et al.* Kinetics of hepatitis B surface antigen decline during 3 years of telbivudine treatment in hepatitis B e antigen-positive patients. *Hepatology* 52, 1611–1620 (2010).

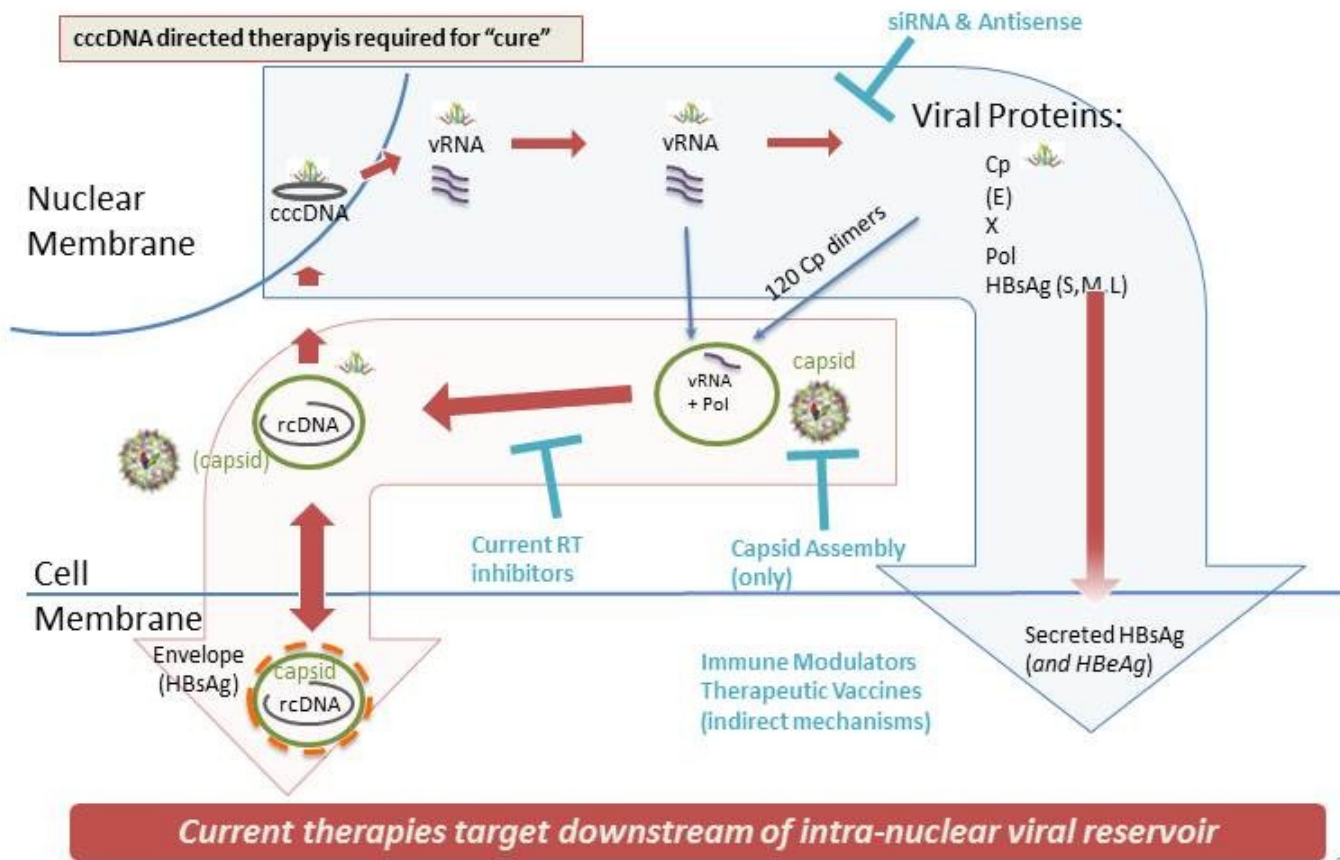
** 2012 EASL HBV Management Guidelines



- **Immunomodulatory (Gilead, Gilead/Globimmune)**
 - Mechanism: Adaptive and innate immune stimulation
 - Immune mediated suppression or clearance of infected cells, and/or
 - Non-specific, poorly understood mechanism of host mediated cccDNA clearance/suppression
 - Risk: Potency (at immune activation) will directly correlate with magnitude and number of adverse events
- **siRNA / Antisense (Arrowhead, Alnylam, Tekmira, ISIS)**
 - Mechanism: DICER/Argonaut degradation of viral RNA, reducing RNA-to-protein translation
 - Result: Reduction in viral antigens and viral load, but no effect on established cccDNA
- **Capsid Assembly Agonists (Novira, J&J, Roche, Hecpharm-China)**
 - Mechanism: Inappropriate enhancement of capsid assembly
 - Result: Potent non-nuc inhibitor of replication

Therapies in clinical trials are showing interesting advances, but are not targeting the viral reservoir directly

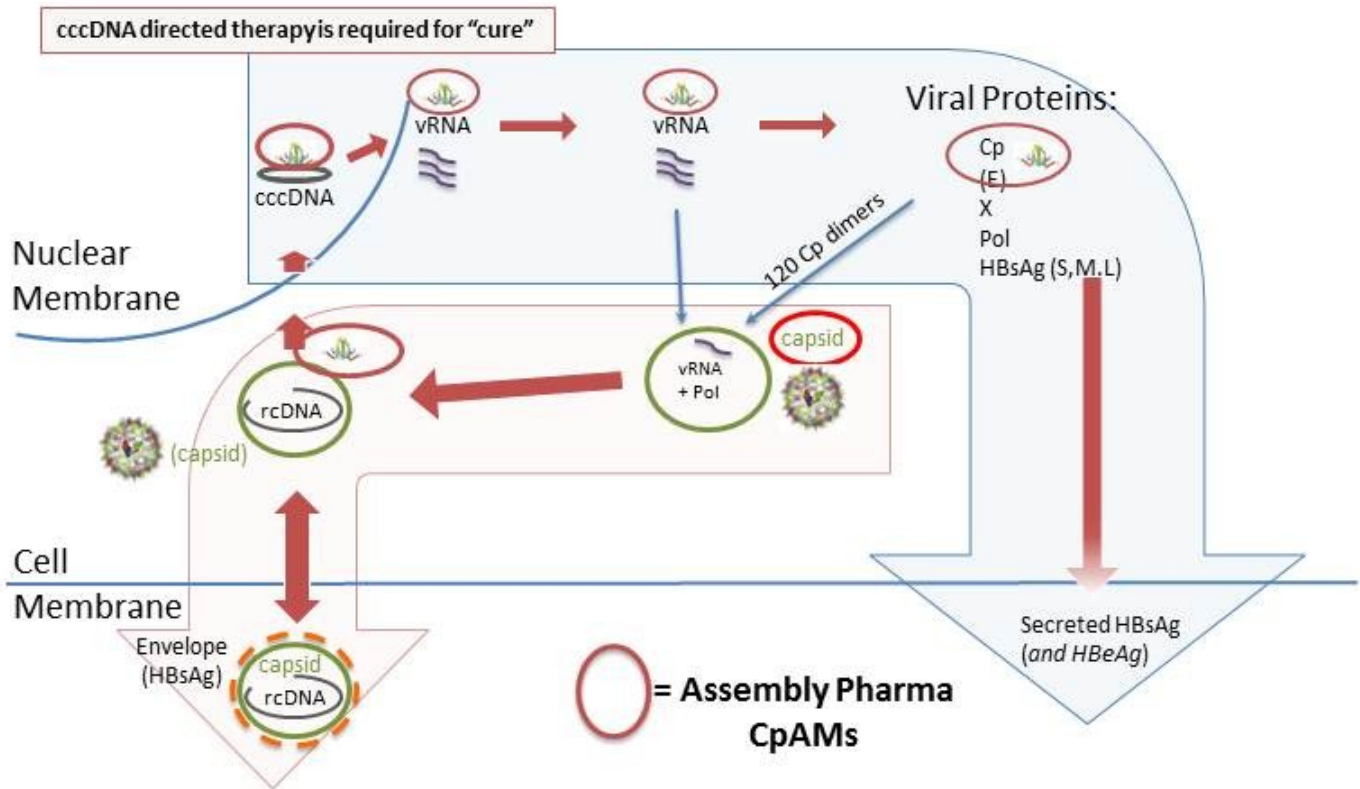
HBV Life Cycle & Current Approaches



Why Core Protein?



HBV Life Cycle – Assembly's CpAM Approach

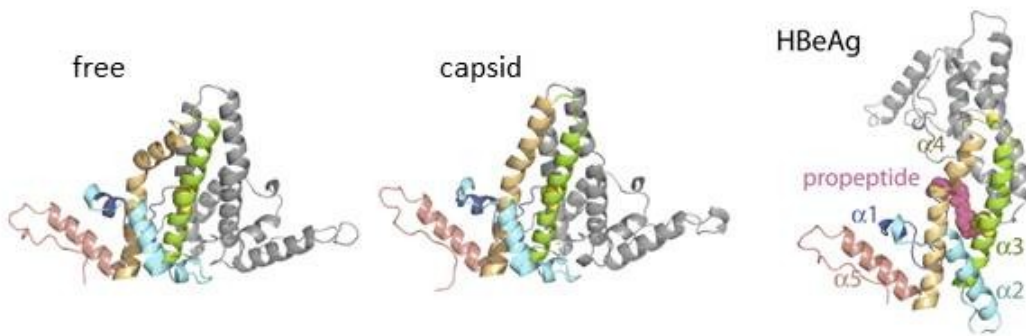


Core Protein is found throughout the lifecycle & importantly at cccDNA

Core Protein – One Target, Many Functions



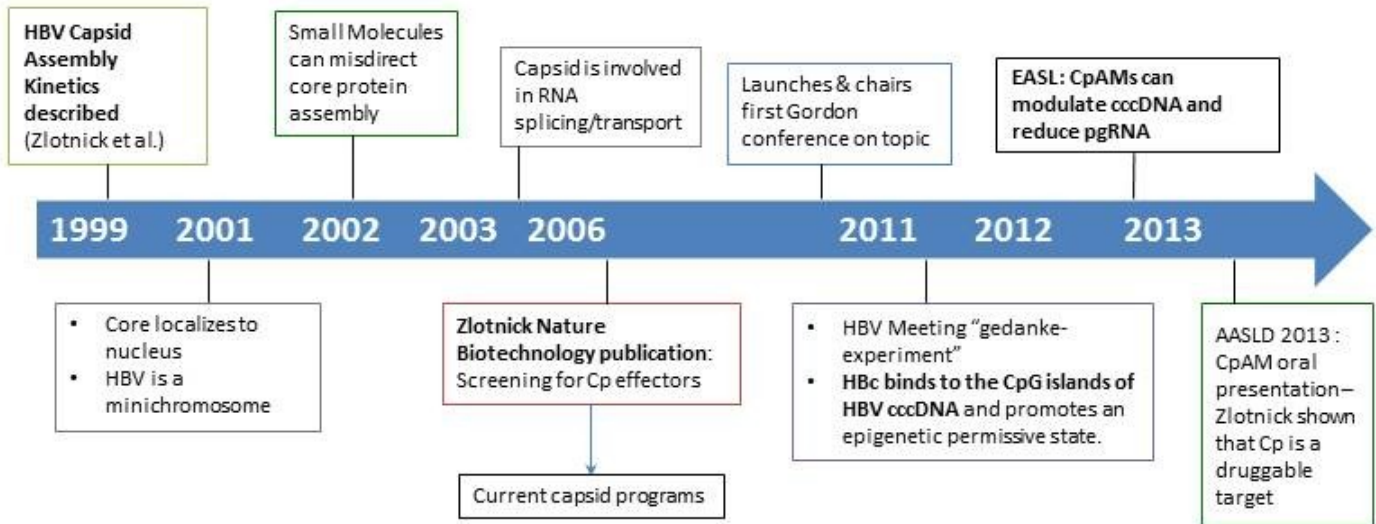
HBV core protein is pleiotropic - it has multiple functions in the HBV lifecycle



Zlotnick, Tan, Seiber, (2003) Structure 21, 6-8.

Deep understanding of core protein is a differentiating advantage for Assembly

Assembly Leadership on Cp is Based on Seminal Research and Current Scientific Leadership of Founder Zlotnick





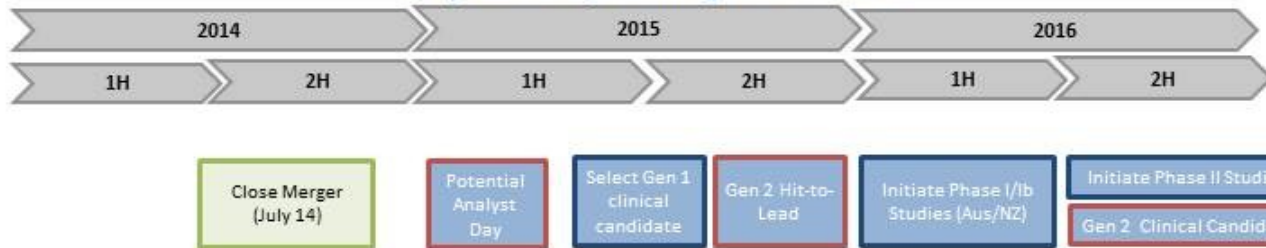
- **Convenience:** Oral
- **Single Agent or Combination Opportunity:**
 - Potential to be combined with other classes of compounds
- **Immunology:**
 - CpAMs are not dependent on immune response, but patients can expect the same benefits as immune modulating approaches if reducing viral antigen and pgRNA supports anti-HBV immunity
- **Efficacy:** Assembly could target CpAMs to multiple aspects of viral lifecycle, resulting in:
 - Reducing viral load
 - Reducing viral pgRNA
 - Reducing viral antigens (HBeAg & HBsAg)
- **Safety:** Direct anti-viral, modulator of a foreign protein

HBV Pipeline & Expected Upcoming Milestones



Product	Disease Area	Discovery	Hits	Stage of Development				
				Lead ID	IND Dev.	Ph I	Ph II	Ph III
CpAM Gen 1	HBV			Over Next ~18 Months				
CpAM Gen 2	HBV			Over Next ~18 Months				

Expected Upcoming Milestones





The patent applications fall broadly into two categories:

1. Platform patent applications

- Multiple platform patent applications filed, with others in process
- Patent applications cover novel mechanism of action, methods of treatment, novel assays, and others

2. Composition of matter patent applications

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

- *We are currently in the process of preparing multiple additional filings*
- *Our patent portfolio is intended to cover significant geography in HBV*

Microbiome Program: *C. difficile*





- We have in-licensed technology for targeted delivery of complex agents to select regions of the GI tract
- Our delivery technology exploits specific pH gradients in the gut and new coating technologies in conjunction with state of the art encapsulation technology
 - This is designed to deliver complex agents to the proximal colon and/or terminal ileum
- **Precedent** - *C. difficile* infection provides an excellent path for potentially curative therapy using microbiome approach
 - Major health problem and increasing in incidence
 - Stunning success of FMT
 - Durable cure within 24hrs
 - Success reported with at least 2 different mixtures of bacterial strains
- By providing the benefits found in current FMT, using selected strains in an oral-capsule based therapy we aim to increase clinical adoption with a simple path for re-imburement by payers



Research Plan:

- Identification of lead candidates from successful FMT patients (Brown, RI) by MIT, Roswell Park, Buffalo U.
- Parallel completion of CMC development to be ready for IND, and then commercial supply for PH IIb/III

Expected Milestones

- Proof of Principle for coating fastidious anaerobe Q3-4 2014
- Strain leads identified mid 2015
- IND end 2015; clinical data 3Q 2016

Patents:

- Multiple novel delivery patents filed in 2013
- Other microbiome specific applications in process

ASMB Combined HBV & Microbiome Pipeline



Product	Disease Area	Discovery	Hits	Current & Planned Stage of Development				
				Lead ID	IND Dev.	Ph I	Ph II	Ph III
CpAM Gen 1	HBV	[Green bar]		[Blue bar: Over Next ~18 Months]				
CpAM Gen 2	HBV	[Green bar]	[Blue bar: Over Next ~18 Months]					
MB Gen 1	C. difficile	[Green bar]	[Blue bar: Over Next ~18 Months]					
CpAM Other	Other Virus (TBD)	[Grey bar: TBD]	<p>Rich science at the Core Protein and Microbiome Therapeutics provides basis for future development of multiple products into other ID targets</p>					
MB Other	Other Indication (TBD)	[Grey bar: TBD]						



- **Nasdaq: ASMB**
- **~\$20 mm on balance sheet (6/30/2014)**
- **Cash runway enables multiple milestones into Q4-2015 under current development plan**
 - *Current S-3 filing provides flexibility to opportunistically access the capital markets*
- **Approximately 8.6 mm shares outstanding**
- **Fully diluted 11.8 mm shares**



Two Proprietary Technology Platforms

Infectious Disease Focused ➔ Potential Curative Therapy for *Hepatitis B* and *Clostridium difficile*

Pipeline Offers First-in-class and Best-in-class Product Opportunities

Experienced Management and R&D Team

Cash Allows Achievement of Valuable Milestones

Flexibility to Opportunistically Access Capital Markets