

Developing Innovative
Therapies for Unmet Medical
Needs in Brain Diseases



Symbinas Pharmaceuticals

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This Is Not An Offer To
Sell Securities of Symbinas
Pharmaceuticals, Inc.

COMPANY



Symbinas Pharmaceuticals Inc. (“Symbinas”) is a privately held, U.S.-based, early-stage biopharmaceutical company dedicated to developing therapeutics to make significant differences in the lives of patients with Concussion and Traumatic Brain Injury worldwide.

OUR STORY

“Why there is still no treatment for concussion?” asked Dr. Hardesh Garg after one of his own family members had concussion and the only treatments given for this serious illness were supportive such as bed rest and pain medicines. Finding that in past decades no real advancement has been made in treating this common and serious disease, he launched Symbinas in 2018 with the purpose of finding treatment for Traumatic Brain Injury. So began our journey to develop novel therapeutics for this global crisis.

What started as a simple question out of concern for his own family member is now becoming a reality. Symbinas is advancing its drug candidate, SMB-603, into intravenous formulation and plans to start clinical trials in patients with TBI next year.

PROBLEM



Traumatic brain injury (TBI) is a large unmet medical need **without any approved treatment.**

Concussion/TBI is a global epidemic effecting **50 million** people each year and is growing. Annual cost is over **\$400 Billion.**

There are an estimated **5.3 million** people in US, **7 million** in Europe, **12 million** in China and **10 million** in India with TBI-related disability

In US, each each year an estimated **2.9 million** Americans sustain a TBI, costing **\$76.5 Billion.** In US alone, as a consequence of these injuries:

50,000
people die

230,000
people are hospitalized

80,000 to 90,000
people experience long-term disability

PROBLEM

- No treatment currently available. Only supportive treatment are prescribed such as bedrest and pain medicines.

- TBI is not an INCIDENT but a **CHRONIC Disease**, causing lifelong side effects such as anxiety, mood disorders, epilepsy, stroke, dementia, Alzheimer's, Parkinson's and CTE

- TBI disables **SIX times more** people each year than spinal cord injuries, multiple sclerosis, HIV/AIDS, and breast cancer **COMBINED**

- TBI is found in over **40% of retired LIVING** NFL players.
- Very common in military, TBI has been called a “**signature injury**” of Iraq and Afghanistan conflicts
- Concussions affect **athletes, veterans, children**, and individuals who have suffered injury through accidents or violence
- The middle or high school athlete who suffered a **non-blackout concussion** may experience symptoms such as insomnia, agitation, depression, memory loss and cognitive decline, and this can become progressively worse over time



*Data from * *Maas A et al. Traumatic brain injury. The Lancet Neurology. 2017 Nov; 16(12):987 – 1048*

Global, regional, and national burden of traumatic brain injury and spinal cord injury, 1990–2016: Lancet Neurol 2019; 18: 56–87

SOLUTION

Currently No approved treatment -- Symbinas is changing this

Only symptoms are currently treated, not brain injury itself



SMB-603 Mitochondrial enhancement and stem cell stimulation by SMB-603 repairs the cellular damage seen in TBI

SMB-710
(drug candidate) Oral, Fixed-dose combination formulation. A multi-modal approach impacting Mitochondrial enhancement and neuroinflammation.

SOLUTION

Our LEAD drug candidate, **SMB-603** to treat TBI, via FDA's accelerated pathways, has a target date for approval within **24 months** after IND



Lower Cost

Average development cost of under \$50M by using already-known molecules compared to more than \$1B for “de novo” drug development.



Faster to Market

With FDA's accelerated pathways, such as 505(b)(2), Fast Track, Emergency Use Authorization, expected target date for **SMB-603 for TBI is within 24 months of IND***



Lower Risk of Failure

Already-know molecules have been safety established, thus lowering the chance of failure (safety issues account for 30-40% of clinical failures).



Higher ROI

FDA's expedited pathways and proven safety profile increase the likelihood of success and thus substantial return on investment.

**IND filing timing dependent on funding*

LEAD DRUG

SMB-603

T h e r a p e u t i c

T a r g e t



- Mitochondrial dysfunction in cerebral tissue is a **central phenomenon** during post-traumatic neurometabolic cascade occurring after primary damage from TBI
- The neurological consequences of **mitochondrial impairment** including neuronal apoptosis, increased fission, axonal injury, production of oxygen free radicals and Blood-brain-barrier disruption are well documented
- This **mitochondrial-targeted neuroenhancement and neuroprotection** leads to improvements in long-term complications of concussions and TBI.
- Studies show that small-molecule ingredient in SMB-603 improves the pathophysiological changes and symptoms seen in TBI, including cognitive, memory, emotional, motor and sensory symptoms

SAFETY AND EFFICACY DATA

SMB-603



ANIMAL EFFICACY DATA:

Over 30 published studies showing strong animal **efficacy data** in TBI animal models



HUMAN SAFETY PROFILE:

Safety well established in humans. On market for over 10 years with **proven safety profile in human use globally**. It has been marketed in dozens of countries around the world



HUMAN EFFICACY DATA:

Case report efficacy data obtained in patients with TBI using SMB-603 and SMB-001, alone and in combination

Note: detailed drug data information provided in Science deck

FINANCIAL PROJECTIONS

SMB-603

2,900,000	Annual US traumatic brain injuries	2,900,000
2,175,000	mild TBI cases (75%)	2,175,000
5%	Penetration rate	10%
108,750	Annual patients treated	217,500
	Price per treatment	
\$ 5,000	(\$250/dose, twice a day for 10-days)	\$ 5,000
\$ 543,750,000	Annual revenue	\$ 1,087,500,000

SMB-603

\$543-1,087 million in US alone



DEVELOPMENT PLAN

First 100 days

- Pre-IND meeting with FDA
- Formulation development and CMC data
- Continue to seek synergistic “Pharma” partners for drug development and commercialization

Next 6 to 9 months

- File additional Patents
- Finalize Formulations, CMC data and animal toxicity studies
- Continue to seek synergistic “Pharma” partners for drug development and commercialization
- IND approval from FDA

Following 12 months

- Manufacture cGMP Clinical Trial Batch of Intravenous SMB-603
- Conduct Fast-Track Clinical Trial under FDA’s special pathways
- Out-license or Partnership to commercialize SMB-603

OUR TEAM - Management



Dr. Hardesh Garg

*Founder, CEO and
Chairman*

Experienced purpose-driven physician and seasoned entrepreneur. Expert in Clinical Development, Regenerative Medicine and Stem Cells. A researcher, clinician and innovator in healthcare and life sciences. Well experienced in clinical trials, product development and regulatory affairs



Tyler Currie

*SVP, Business
Development*

Diversified operations leadership and strategic partnerships in 30 countries, including previous executive roles in MedTech, professional sports and management consulting. Proven experience in marketing, athletic engagement, partnerships and government relations.

pending agreement

*Executive Advisor,
Corporate Development*

Proven experience as a CEO in public and private companies. Expert in financial management, modeling, fundraising, systems and controls. Served as senior CXO executive for several private and public life-sciences and biotech companies

OUR TEAM - Advisors

Dr. Jeffrey Cummings

*Consultant Advisor,
Clinical Programs*

Professor of Medicine (Neurology) at Cleveland Clinic and Founding Director of Lou Ruvo Center for Brain Health in Las Vegas. Internationally renowned authority in clinical research and development in neurosciences.

Dr. Todd Schwedt

*Consultant Advisor,
Clinical Programs*

Professor of Neurology at Mayo Clinic. He is Chair of Neurology Research at Mayo Clinic and board of trustees at International Headache Society. Well versed in concussion/TBI, clinical research and modeling brain imaging data.

Dr. Brent Masel

*Consultant Advisor,
Clinical Programs*

Clinical Professor of Neurology, University of Texas Medical Branch in Galveston and National Medical Director at Brain Injury Association of America

Dr. Andrew Badley

*Consultant Advisor,
Clinical Programs*

Professor of Infectious Diseases at world-renowned Mayo Clinic. Chair Mayo Clinic COVID Research task force and Chair of Molecular Medicine. Expert in infectious diseases and clinical trials in COVID-19.

Dr. Rodrigo Machado-Vieira

*Consultant Advisor,
Clinical Programs*

Professor of Psychiatry at McGovern Medical School University of Texas Science Center in Houston. Proven expert in translational research, he was the Director of the Translational Research Clinic at the National Institute of Health (NIH).

Dr. Barry Zingman

*Consultant Advisor,
Clinical Programs*

Professor of Medicine at Albert Einstein College of Medicine, Clinical Director of Infectious Diseases at Montefiore Medical Center, Principal Investigator of NIH Adaptive COVID-19 Treatment Trial (ACT Trial), renowned authority in infectious diseases.

Dr. You-wen He

*Consultant Advisor,
Scientific Programs*

Professor of Immunology at Duke University Medical Center. Expert in immunotherapy, vaccines, and molecular biology. Research areas include both innate and adaptive immunity against viral and bacterial infections as well as tumors.

T H A N K / Y O U



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