**Commercial Funding Program**

### Background

As part of its 2006-2010 strategic response to MS, the National MS Society created Fast Forward for the purpose of supporting commercial organizations engaged in the development of new therapies and diagnostic tools for MS. Fast Forward bridges the preclinical commercial funding gap by targeting funds to de-risk therapeutic development. Our goal is to catalyze outside investment by funding critical work needed to position projects for subsequent commercial development.

### Organization and Funding History

Original funding for Fast Forward was derived from over $6 million in philanthropic contributions to the Society. Funding to date exceeds $21 million.

**$21.5 Million**

- 443 proposals reviewed
- 33 company projects and
- 13 academic projects funded

**Notable milestones for Fast Forward organizational progress:**

- **January 2009** – First agreement funded (Apitope International)
- **March 2009** – 5-year strategic partnership with EMD Serono - Merck KGaA launched
- **December 2009** – Project co-funded with Juvenile Diabetes Research Foundation to support early development of potential therapy for MS and Type 1 Diabetes.
- **September 2010** – $1 million Strategic Partnership established with Italian MS Society
- **July 2012** – 3-year research sponsorship with Conrad Hilton Foundation established
- **February 2016** – Research Showcase Meeting sponsored by Sanofi Genzyme convened
- **January 2019** – Glixogen Therapeutics formed by FutuRx to develop Society-funded technology
- **July 2019** – MedaRed Inc. raises $6.5 million from Dementia Discovery Fund

### Process

Similar to our Research Grant peer review process, Fast Forward engages the brightest minds in MS research to evaluate the scientific merit of proposals. In addition, industry advisors and consultants are brought into the review to ensure that projects are positioned to be viable candidates for future commercial development.

- Applications are received through an annual request for proposals (RFP). The RFP subject is determined by staff (with the vetting of Society research leadership) and aligns with Society priorities. Companies and academic researchers are eligible to apply.
- Proposals are reviewed by a Scientific and Business Advisory Committee (SBAC) which considers the strength of the science and the viability of the business plan.
- Milestone-based research agreements are developed for meritorious proposals. A financial return for the Society is also negotiated contingent on future commercial success.
- The Fast Forward Board of Managers provides oversight.
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Current portfolio
A diverse array of projects have been funded through Fast Forward, including cell-based therapies, biologics and small molecules. The program has also funded diagnostic and biomarker validation work, in addition to therapies to address MS symptoms. Much of our portfolio is focused on small molecules in early preclinical stages of development. As the Fast Forward program is fully aligned with Society Research Priorities, in recent years, there has been an emphasis on funding approaches in neuroprotection and repair in response to the unmet need, particularly for progressive forms of MS. Many projects that we see are derived from initial work within the academic research portfolio, and most take advantage of connections to investigators funded by the Society. We anticipate future projects in non-pharmacologic approaches, especially those utilizing digital medicine and rehabilitative technologies. Of the 46 projects funded to date, 10 remain active (R&D still in progress towards identified milestones) and 4 new meritorious awards are in negotiation.

How we measure success
The time and cost of developing a new therapy is considerable. For example, the Tufts University Center for the Study of Drug Development indicates it costs between $161 million and $2 billion to bring a new drug to market. According to Pharmaceutical Benchmarking Forum, only 6% of projects in preclinical development survive clinical evaluation to regulatory approval. The high cost and failure rate present challenges for small companies seeking funding. They may not be far enough along in the drug development process to attract traditional venture capital or pharma investors, but may be too far in the process to access most federal and foundation funding sources aimed at more basic research. Fast Forward is positioned to fill this funding gap; enabling small companies to complete key preclinical and early clinical studies needed to attract additional stakeholders. Given that Fast Forward projects typically start in the pre-clinical development stages, our relevant metrics focus on project advancement through the development pathway, consummation of licensing agreements or corporate partnerships, and other follow-on financing events as benchmarks for success. Since Fast Forward does not have the capacity to take individual projects through the entire clinical
FastForward Commercial Funding Program

development process to approval, our goal is catalyze outside investment by funding critical work needed to better-position projects for subsequent commercial development.

Accomplishments
Many recipients of Fast Forward funding indicate the synergistic effect of the award. The process of vetting projects by our thorough and diligent review affords the recipient organization scientific and commercial validation of their work. A few examples of successful projects, their Fast Forward funding and subsequent development, are shown below.

### Metrics for success
- Funded R&D milestones completed
- Licensing / Partnership
- Follow-on financing
- IND / Clinical trials initiated

#### MedaRed, Inc.
**Anti-Fibrin Monoclonal Antibody Humanization**
- Fast Forward $330,000
- $6.5 Million financing
  - Dementia Discovery Fund
  - Dolby Family Ventures

#### Karyopharm Therapeutics
**Proof of concept / toxicology studies – KPT-350**
- Fast Forward $500,000
- $250M asset purchase
  - Biogen

#### bionure
**IND-enabling studies of BN201**
- Fast Forward $988,484
- Successful Phase 1 Study for Lead Candidate BN201
  - May 2019

Return on Investment
Although all research awards allow the opportunity for the Society to share revenue should a technology ultimately attain commercial success, awards through Fast Forward are granted with explicit conditions of financial return based on achievement of commercial development milestones. However, financial return is a secondary consideration; it is not a component of the scientific and business review process. The primary objective of funded commercial research is to positively impact the lives of people affected by MS. Therefore the financial return component is implemented during the research contract negotiation phase after a project is determined to be meritorious for funding. Oversight regarding terms for financial return is provided by the Fast Forward Board of Managers.

The Society has received **$7.5 Million** from 5 companies that achieved commercial milestones
Promoting the Translation of Society Academic Research Projects
Fast Forward has a strong interest in promoting the translation of findings originating from the various Society research grant programs into commercial products. In response to this objective, we have expanded the Fast Forward program to include proposals from academic investigators. Conducting commercial R&D in an academic environment is challenging because infrastructure may not be in place to carry out many of the studies needed for drug discovery work. Academic investigators may have an incomplete understanding of the steps needed for commercial development. Fortunately, an increasing number of academic institutions are providing additional resources and often our academic investigators are able to use consultants and contract research organizations for Fast Forward projects to cover particular needs. Since expanding the program, the proportion of applications from academic investigators has been increasing. Contacting Fast Forward Fast Forward is always interested in talking with companies and academic investigators working on therapeutics, devices and diagnostics for people living with MS. We often communicate with companies on an ongoing basis, providing feedback and assisting with connections even before they are ready to respond to an appropriate RFP.

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