Solid Biosciences, LLC Logo

Solid Biosciences Reports Second Quarter 2018 Financial Results and Provides Business Update

August 10, 2018

- IGNITE DMD Phase I/II Clinical Trial Patient Screening Has Resumed -

CAMBRIDGE, Mass., Aug. 10, 2018 (GLOBE NEWSWIRE) -- Solid Biosciences Inc. (NASDAQ:SLDB) today reported financial results for the second quarter ended June 30, 2018 and provided a business update.

“It is an exciting time for Solid as we work to advance our innovative pipeline designed to address Duchenne muscular dystrophy for all patients with this devastating disease,” said Ilan Ganot, Chief Executive Officer, President and Founder of Solid Biosciences. “We look forward to dosing additional patients with our microdystrophin gene therapy candidate, SGT-001, in IGNITE DMD at the University of Florida, where patient screening is now underway. We also continue to build upon our scalable GMP manufacturing process and capabilities so that we are well positioned to bring this potentially transformative therapy to patients, if approved.”

Recent Developments

- Announced in June that the U.S. Food and Drug Administration (FDA) lifted the clinical hold on IGNITE DMD, Solid’s Phase I/II clinical trial for SGT-001 for the treatment of Duchenne muscular dystrophy (DMD). In connection with the lifting of the clinical hold, Solid made changes to the IGNITE DMD protocol, including adding an enhanced glucocorticoid regimen and additional monitoring measures, as well as a specification that eculizumab should be available as a treatment option if complement activation is observed in future patients. The Company plans to enroll and dose several children prior to dosing additional adolescents and now has the choice to obtain an intermediate muscle biopsy at 45 days post administration of SGT-001.

- Received approval from the University of Florida Investigational Review Board (IRB) and resumed patient screening in IGNITE DMD at the University.

- Announced new preclinical data for SGT-001 at the 21st Annual Meeting of the American Society of Gene and Cell Therapy in May, which further demonstrated its potential to be an important treatment approach for DMD. Specifically, long-term preclinical data demonstrated that a single intravenous administration of a low, medium or high dose of SGT-001 resulted in body-wide microdystrophin transgene expression that was sustained for at least 30 months, as well as restoration of key microdystrophin-associated proteins, including neuronal nitric oxide synthase (nNOS). In a different study, the restoration of nNOS and associated activity were shown to result in improvements in muscle histopathology and function in preclinical models, suggesting that nNOS activity could serve as an important marker of molecular function.

- Announced in June that the Company expanded its clinical development expertise with the appointment of biopharmaceutical veteran Martin Freed, M.D., F.A.C.P., to its Board of Directors. Dr. Freed brings to Solid more than 25 years of strategic development and operational expertise from across the biopharmaceutical and life sciences industries. In addition, Ilan Ganot assumed the role of President after the retirement of Gilad Hayeem from his role as President and Director.

- Continued to progress its exploratory pipeline of next generation gene therapy assets, as well as its biomarker work intended to improve drug discovery and clinical development. This work includes an agreement with Flagship Biosciences to validate the use of its computational Tissue Analysis (cTA™) platform to quantify SGT-001-produced microdystrophin and additional signature proteins localized to the muscle membrane, such as nNOS, as supportive measures of microdystrophin function in IGNITE DMD.

Anticipated Milestones

- Continue to advance IGNITE DMD with the dosing of additional patients in the coming months and expanding the clinical trial footprint with additional sites both in the U.S. and abroad. The Company remains on track to communicate initial data from a pre-specified interim analysis in the second half of 2019.

- Progress the Company’s anti-LTBP4 monoclonal antibody program intended to reduce fibrosis and inflammation in the muscle. Solid continues development of its lead antibodies and remains on track to initiate preclinical activities by year end 2018.

Financial Highlights

Solid Biosciences reported a net loss of $18.0 million for the second quarter of 2018 as compared to $11.3 million for the second quarter of 2017. The increase in net loss for the year was due to increased research and development expenses, as well as investments in the Company’s infrastructure.

Research and development expenses for the second quarter of 2018 were $13.6 million as compared to $8.6 million for the prior year period. The

increase in research and development expenses was primarily driven by compensation and other costs associated with additional headcount, as well as facility costs and increased costs related to the clinical development and manufacturing activities for SGT-001. These increases were offset by a reduction in the preclinical costs associated with SGT-001.

General and administrative expenses were $4.6 million for the second quarter of 2018 as compared to $3.3 million for the prior year period. The increase in general and administrative expenses was primarily due to personnel and facility related costs, as well as other corporate expenses.

Solid ended the second quarter of 2018 with $162.8 million in cash, cash equivalents and available-for-sale securities as compared to $69.1 million as of December 31, 2017. The increase was primarily the result of the completion of the Company's initial public offering on January 30, 2018.

About SGT-001
Solid's lead candidate, SGT-001, is a novel adeno-associated viral (AAV) vector-mediated gene transfer under investigation for its ability to address the underlying genetic cause of Duchenne muscular dystrophy (DMD), mutations in the dystrophin gene that result in the absence or near-absence of dystrophin protein. SGT-001 is a systemically administered candidate that delivers a synthetic dystrophin transgene, called microdystrophin, to the body. This microdystrophin encodes for a functional protein surrogate that is expressed in muscles and stabilizes essential associated proteins, including neuronal nitric oxide synthase (nNOS). SGT-001 utilizes AAV9, which has an affinity for muscle and is currently being evaluated in multiple clinical programs in other indications. Data from Solid's preclinical program suggest that SGT-001 has the potential to slow or stop the progression of DMD, regardless of genetic mutation or disease stage.

SGT-001 is based on pioneering research in dystrophin biology by Dr. Jeffrey Chamberlain of the University of Washington and Dr. Dongsheng Duan of the University of Missouri. SGT-001 has been granted Rare Pediatric Disease Designation, or RPDD, in the United States and Orphan Drug Designations in both the United States and European Union.

About Solid Biosciences
Solid Biosciences is a life science company focused solely on finding meaningful therapies for Duchenne muscular dystrophy (DMD). Founded by those touched by the disease, Solid is a center of excellence for DMD, bringing together experts in science, technology and care to drive forward a portfolio of candidates that have life-changing potential. Currently, Solid is progressing programs across four scientific platforms: Corrective Therapies, Disease-Modifying Therapies, Disease Understanding and Assistive Devices. For more information, please visit www.solidbio.com.

Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding Solid's IGNITE DMD clinical trial, its anticipated achievement of milestones and the potential of SGT-001. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. These risks and uncertainties include, but are not limited to, risks associated with Solid's ability to obtain and maintain necessary approvals from the FDA and other regulatory authorities and investigational review boards at clinical trial sites; enroll patients in its clinical trials; continue to advance SGT-001 in clinical trials; replicate in later clinical trials positive results found in preclinical studies and earlier stages of clinical development; advance the development of its product candidates under the timelines it anticipates in current and future clinical trials; obtain, maintain or protect intellectual property rights related to its product candidates; compete successfully with other companies that are seeking to develop DMD treatments and gene therapies; manage expenses; and raise the substantial additional capital needed to achieve its business objectives. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the "Risk Factors" section, as well as discussions of potential risks, uncertainties and other important factors, in the Company's most recent filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof and should not be relied upon as representing the Company's views as of any date subsequent to the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so.

Solid Biosciences Inc.
Condensed Consolidated Statements of Operations
(unaudited, in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	13,594	8,607	25,523	17,340
General and administrative	4,584	3,280	8,628	8,660
Total operating expenses	18,178	11,887	34,151	26,000
Loss from operations	(18,178)	(11,887)	(34,151)	(26,000)
Other income (expense):				
Revaluation of preferred unit tranche rights	-	20	-	20
Interest income	80	52	145	114
Other income	118	504	149	680
Total other income (expense), net	198	576	294	814
Net loss	(17,980)	(11,311)	(33,857)	(25,186)
Net loss attributable to non-controlling interest	-	-	-	(1,060)
Net loss attributable to Solid Biosciences Inc.	(17,980)	(11,311)	(33,857)	(24,126)

Accretion of preferred units to redemption value	-	-	-	(959)
Redemption of preferred units	-	-	-	15,685
Redemption of redeemable interest from non-controlling interest in Solid GT	-	-	-	(1,925)
Net loss attributable to common stockholders	$ (17,980)	$ (11,311)	$ (33,857)	$ (11,325)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.52)	$ (0.66)	$ (1.06)	$ (1.12)
Weighted average shares of common stock outstanding, basic and diluted	34,449,758	17,041,311	31,916,295	10,083,502

Solid Biosciences Inc.
Condensed Consolidated Balance Sheets
(unaudited, in thousands, except share and per share data)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 145,824	$ 52,080
Available-for-sale securities	16,935	17,014
Prepaid expenses and other current assets	1,714	1,499
Restricted cash	-	65
Total current assets	164,473	70,658
Property and equipment, net	6,551	2,429
Other non-current assets	209	-
Restricted cash	237	-
Deferred offering costs	-	3,106
Total assets	$ 171,470	$ 76,193
Liabilities, Preferred Units and Stockholders' / Members' Equity / (Deficit)		
Current liabilities:		
Accounts payable	$ 3,741	$ 5,066
Accrued expenses and other current liabilities	4,938	6,205
Total current liabilities	8,679	11,271
Other non-current liabilities	499	-
Total liabilities	9,178	11,271
Series 2 Senior Preferred Units	-	55,002
Series 1 Senior Preferred Units	-	25,000
Junior Preferred Units	-	44,177
Stockholders' / Members' Equity / (Deficit)		
Series A, B, C and D Common Units	-	65,014
Common Stock	35	-
Additional paid-in capital	320,382	-
Accumulated other comprehensive loss	(10)	(13)
Accumulated deficit	(158,115)	(124,258)
Total stockholders' / members' equity (deficit)	162,292	(59,257)
Total liabilities, preferred units and stockholders' / members' equity	$ 171,470	$ 76,193

Media Contact:
Solid Biosciences
Kate Niazi-Sai
617-337-4680
media@solidbio.com

Investor Contact:
Kendall Investor Relations
Carlo Tanzi, Ph.D.
617-337-4680
investors@solidbio.com


Primary Logo

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