Solid Biosciences Reports Second Quarter 2019 Financial Results and Provides Business Update

August 14, 2019

– Additional patient dosed at 2E14 vg/kg in second cohort of IGNITE DMD trial –

– Study protocol amended to expedite clinical execution of SGT-001 –

– Recent $60M capital raise extends runway into the fourth quarter of 2020 –

CAMBRIDGE, Mass., Aug. 14, 2019 (GLOBE NEWSWIRE) -- Solid Biosciences Inc. (Nasdaq: SLDB) today reported financial results for the second quarter ended June 30, 2019 and provided a business update.

“We continue to execute on our mission to bring transformative therapies to patients with Duchenne muscular dystrophy, and we have taken several steps towards reaching our goal,” said Ilan Ganot, Chief Executive Officer, President and Co-Founder of Solid Biosciences. “We have amended the IGNITE-DMD protocol to expedite our clinical path evaluating our SGT-001 gene transfer candidate and have treated a second patient in our higher dose cohort. We also bolstered our financial resources and extended our runway. Looking forward, we continue to anticipate providing a data update from the IGNITE DMD clinical trial in the months ahead.”

Recent Developments

- Solid has amended the IGNITE DMD Phase I/II trial protocol for SGT-001, an adeno-associated viral gene transfer candidate under investigation for Duchenne muscular dystrophy (DMD). The changes to the protocol include adding an upper weight limit of 25 kg for at least the next patient dosed in the second cohort and removing the matched patient control arm for the rest of the second cohort in the IGNITE DMD trial. Solid expects that these protocol updates will expedite the path to obtaining IGNITE DMD clinical trial results as well as the broader development of the SGT-001 program. Solid remains committed to dosing larger patients in the future. The company intends to provide a data update from the ongoing IGNITE DMD clinical trial later this year.
- Today, Solid announced that the second patient has been dosed in the higher dose cohort of the IGNITE DMD clinical trial.
- As announced previously, the company raised $60 million through a private placement, which closed on July 30, 2019. Participants included a mix of new and existing investors, including Perceptive Advisors, LLC; Boxer Capital, LLC; EcoR1 Capital, LLC; Bain Capital Life Sciences; RA Capital Management; Waverly Capital; Invus and certain board members and executive officers.

Financial Highlights

Research and development expenses for the second quarter of 2019 were $21.6 million, compared to $13.6 million for the second quarter of 2018. The increase was primarily attributable to 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.

General and administrative expenses for the second quarter of 2019 were $5.4 million, compared to $4.6 million for the second quarter of 2018. The increase was primarily attributable to increased personnel costs, partially offset by a decrease in other corporate expenses.

Net loss for the second quarter of 2019 was $26.5 million, compared to $18.0 million for the second quarter of 2018.

Solid had $67.4 million in cash, cash equivalents and available-for-sale securities as of June 30, 2019, compared to $122.5 million as of December 31, 2018. Including the proceeds from the July 2019 private placement, Solid expects that that company has sufficient capital to fund its operations into the fourth quarter of 2020.

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, and Fast Track Designation 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. 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 our expectations regarding the IGNITE DMD clinical trial, the safety or potential efficacy of SGT-001, the sufficiency of our cash, cash equivalents and investments to fund our operation and other statements containing the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would,” and similar expressions. 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, including to proceed with dose escalation of IGNITE DMD; replicate in 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; successfully scale its manufacturing process; 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,	
	2019	2018	2019	2018
Revenue	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	21,610	13,594	44,879	25,523
General and administrative	5,359	4,584	12,392	8,628
Total operating expenses	26,969	18,178	57,271	34,151
Loss from operations	(26,969)	(18,178)	(57,271)	(34,151)
Other income (expense):				
Interest income	367	80	875	145
Other income	77	118	289	149
Total other income (expense), net	444	198	1,164	294
Net loss	$ (26,525)	$ (17,980)	$ (56,107)	$ (33,857)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.76)	$ (0.52)	$ (1.61)	$ (1.06)
Weighted average shares of common stock outstanding, basic and diluted	34,843,344	34,449,758	34,810,101	31,916,295

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

	June 30, 2019	December 31, 2018
Assets		

Current assets:		
Cash and cash equivalents	$ 51,836	$ 86,366
Available-for-sale securities	15,550	36,098
Prepaid expenses and other current assets	10,935	6,175
Total current assets	78,321	128,639
Property and equipment, net	11,829	10,422
Operating lease, right-of-use assets	5,618	-
Other non-current assets	209	209
Restricted cash	327	327
Total assets	$ 96,304	$ 139,597
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,600	$ 3,691
Accrued expenses	6,007	8,235
Operating lease liabilities	1,610	-
Finance lease liabilities	176	173
Other current liabilities	278	382
Total current liabilities	13,671	12,481
Operating lease liabilities, excluding current portion	5,309	-
Finance lease liabilities, excluding current portion	829	859
Other non-current liabilities	-	1,074
Total liabilities	19,809	14,414
Common Stock	35	35
Additional paid-in capital	331,620	324,209
Accumulated other comprehensive gain (loss)	3	(5)
Accumulated deficit	(255,163)	(199,056)
Total stockholders' equity	76,495	125,183
Total liabilities and stockholders' equity	$ 96,304	$ 139,597

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Source: Solid Biosciences Inc.