Solid Biosciences Reports Third Quarter 2024 Financial Results and Provides Business Updates

November 6, 2024

*- **Duchenne:** Dosing completed for first three patients in INSPIRE DUCHENNE clinical trial; SGT-003 has been well tolerated in all patients with no SAEs observed; initial three patient data expected Q1 2025 -*

*- **Duchenne:** Activities undertaken to accelerate development of SGT-003, including: expansion of study protocol in September 2024, activation of additional clinical sites in Q4 2024, additional manufacturing supply to support expanded trial enrollment -*

*- **CPVT:** SGT-501 IND submission for the treatment of catecholaminergic polymorphic ventricular tachycardia (CPVT) on track for 1H 2025 -*

*- **Cash:** Company ends Q3 2024 with approximately $171.1 million in cash, cash equivalents, and available-for-sale securities; Solid has anticipated cash runway into 2026 -*

CHARLESTOWN, Mass., Nov. 06, 2024 (GLOBE NEWSWIRE) -- Solid Biosciences Inc. (Nasdaq: SLDB) (the "Company" or "Solid"), a life sciences company developing precision genetic medicines for neuromuscular and cardiac diseases, today reported financial results for the third quarter ended September 30, 2024, and provided a business update.

"We are highly encouraged by the progress we have made with the INSPIRE DUCHENNE clinical trial over the past quarter, including the activation of University of California, Davis as a clinical site in October," said Bo Cumbo, President and CEO, Solid Biosciences. "SGT-003 continues to be well tolerated in the first three patients dosed. As a result of encouraging early results observed in these patients, we have implemented an updated study protocol amending the clinical trial across key parameters, including enrollment size, age range, and clinical endpoint timelines. With these changes, along with other planned studies, we believe our clinical development program provides significant flexibility in pursuing potential regulatory pathways, with the goal of accelerating a new treatment option to this underserved patient community. We are currently enrolling patients under the expanded INSPIRE DUCHENNE protocol and will continue dosing throughout the rest of 2024 and into 2025."

Mr. Cumbo continued: "We are committed to presenting clinical data in a thoughtful way that will benefit the Duchenne field and community at large, and we will present safety, expression and biomarker data from the first three patients, along with a trial update, in the first quarter of 2025 following the completion and collective assessment of 90-day muscle biopsies."

"Turning to our cardiac pipeline, we are pleased to share that our IND-enabling, GLP toxicology and proof-of-concept studies for CPVT are progressing as expected, with an anticipated IND submission for SGT-501 in the first half of 2025," said Gabriel Brooks, M.D., Chief Medical Officer, Solid Biosciences. "Based upon our positive pre-IND meeting with the U.S. Food and Drug Administration (FDA), we are confident that we have a path to rapidly advance this program to the clinic. CPVT is an underdiagnosed and highly malignant, genetic arrhythmia syndrome with historic mortality rates reaching as high as 50% by age 35.[1] The treatment landscape has not meaningfully changed in decades, despite the fact that currently available therapies such as beta-blockers and flecainide require a high degree of compliance to be effective, do not treat the underlying cause of the disease, and have multiple unfortunate side effects, including depression, fatigue, weight gain, and impotence. Paradigm-shifting treatments are long overdue for patients and their families, and we believe that our gene therapy has the potential to transform patient care for this disorder for years to come. We look forward to submitting our IND and advancing this program into the clinic, which we believe will mark significant progress toward establishing Solid as a leading cardiac precision genetic medicines company."

Additional Company Highlights

- AAV-SLB101, Solid's proprietary capsid used in SGT-003, continues to be well tolerated in the first three patients dosed in the INSPIRE DUCHENNE study, and was well tolerated in NHP and mouse studies. 13 different academic labs and one corporation have begun utilizing AAV-SLB101.
- Solid continues to advance preclinical studies for TNNT2, BAG3, and other pipeline programs.

Third Quarter 2024 Financial Highlights

- **Cash Position:** Solid had approximately $171.1 million in cash, cash equivalents, and available-for-sale securities as of September 30, 2024, compared to approximately $123.6 million as of December 31, 2023. The Company expects that its cash, cash equivalents, and available-for-sale securities as of September 30, 2024, will enable it to fund its operational runway into 2026, which includes: investment for the expansion of the INSPIRE DUCHENNE clinical trial, additional manufacturing supply and Phase 3 start up activities (pending results from INSPIRE DUCHENNE), as well as ongoing activities related to other pipeline medicines.
- **Research and Development (R&D) Expenses:** R&D expenses for the three months ended

September 30, 2024, were $27.3 million, compared to $16.7 million for the three months ended September 30, 2023. The increase of $10.6 million was due to a $5.8 million increase in development program expenses and other research costs, a $3.1 million increase in costs for SGT-501 primarily related to manufacturing and research costs, a $1.1 million increase in external expenses, and a $0.6 million increase in costs for SGT-003 primarily related to clinical and manufacturing costs.

- **General and Administrative (G&A) Expenses:** G&A expenses for the three months ended September 30, 2024, were $7.9 million, compared to $6.4 million for the three months ended September 30, 2023. The increase of $1.4 million was primarily related to a $1.5 million increase in personnel related costs, and a $0.2 million increase in consulting fees, offset by a $0.3 million decrease in temporary services.
- **Net Loss:** Net loss for the three months ended September 30, 2024, was $32.7 million compared to a net loss of $21.0 million for the same period in 2023. Basic and diluted net loss per share was $0.79 and $1.05 for the three-month periods ended September 30, 2024, and September 30, 2023, respectively.

References

1. Abbas M, et al. Catecholaminergic Polymorphic Ventricular Tachycardia. *Arrhythm Electrophysiol Rev.* 2022; 11:e20.

About Solid Biosciences

Solid Biosciences is a precision genetic medicine company focused on advancing a portfolio of gene therapy candidates including SGT-003 for the treatment of Duchenne muscular dystrophy (Duchenne), SGT-501 for the treatment of catecholaminergic polymorphic ventricular tachycardia (CPVT), AVB-401 for the treatment of BAG3-mediated dilated cardiomyopathy, and additional assets for the treatment of fatal cardiac diseases. Solid is advancing its diverse pipeline across rare neuromuscular and cardiac diseases, bringing together experts in science, technology, disease management, and care. Patient-focused and founded by those directly impacted, Solid's mandate is to improve the daily lives of patients living with these devastating diseases. 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 future expectations, plans and prospects for the company; the ability to successfully achieve and execute on the company's goals, priorities and achieve key clinical milestones; the company's SGT-003 program, including expectations for additional CTA filings, site activations, expanded clinical development, accelerated production of multiple GMP batches of SGT-003, initiation and enrollment in clinical trials, dosing, availability of clinical trial data and potential accelerated approval; the company's expectations for submission of an IND for SGT-501 and to submit additional INDs by the end of 2026; the cash runway of the company and the sufficiency of the Company's cash, cash equivalents, and available-for-sale securities to fund its operations; and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," "working" 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 the company's ability to advance SGT-003, SGT-501, AVB-401 and other preclinical programs and capsid libraries on the timelines expected or at all; obtain and maintain necessary approvals from the FDA and other regulatory authorities; replicate in clinical trials positive results found in preclinical studies and early-stage clinical trials of the company's product candidates; obtain, maintain or protect intellectual property rights related to its product candidates; compete successfully with other companies that are seeking to develop Duchenne and other neuromuscular and cardiac treatments and gene therapies; manage expenses; and raise the substantial additional capital needed, on the timeline necessary, to continue development of SGT-003, SGT-501, AVB-401 and other candidates, achieve its other business objectives and continue as a going concern. 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.

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(tables follow)

SELECTED FINANCIAL INFORMATION (UNAUDITED)

CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands, except share data)	**September 30, 2024**	**December 31, 2023**
Cash and cash equivalents	$ 64,394	$ 74,015

Available-for-sale securities	106,723	49,625
Prepaid expenses and other current assets	8,377	6,094
Operating lease, right-of-use assets	24,859	26,539
Property and equipment, net	5,067	6,624
Other non-current assets	475	209
Restricted cash	1,931	1,833
Total Assets	$ 211,826	$ 164,939
Accounts payable	$ 3,458	$ 2,032
Accrued expenses and other current liabilities	13,227	10,161
Operating lease liabilities	1,718	1,855
Finance lease liabilities	1,051	469
Derivative liabilities	3,400	—
Operating lease liabilities, excluding current portion	21,643	22,707
Finance lease liabilities, excluding current portion	307	1,234
Total stockholders' equity	167,022	126,481
Total Liabilities and Stockholders' Equity	$ 211,826	$ 164,939
Common stock outstanding	38,930	20,387

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS	**Three Months Ended September 30,**		**Nine Months Ended September 30,**	
(in thousands, except per share data)	**2024**	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 27,327	$ 16,702	$ 65,661	$ 61,110
General and administrative	7,855	6,412	24,171	20,940
Restructuring charges	—	—	—	(63)
Total operating expenses	35,182	23,114	89,832	81,987
Loss from operations	(35,182)	(23,114)	(89,832)	(81,987)
Other income, net:				
Interest income	2,328	1,962	7,544	5,822
Interest expense	(82)	(106)	(265)	(339)
Other income, net	211	278	453	825
Total other income, net	2,457	2,134	7,732	6,308
Net loss	$ (32,725)	$ (20,980)	$ (82,100)	$ (75,679)
Net loss per share, basic and diluted	$ (0.79)	$ (1.05)	$ (2.04)	$ (3.83)
Weighted average shares of common stock outstanding basic and diluted	41,443,317	20,059,641	40,182,303	19,767,174

Source: Solid Biosciences Inc.