Avidity Biosciences Reports Third Quarter 2025 Financial Results and Recent Highlights

Announced Novartis agreement to acquire Avidity for total equity value of approximately$12 billion; Avidity expects to separate its early-stage precision cardiology programs into a new public company ("SpinCo")

Clear path forward aligned with FDA following pre-BLA meeting for del-zota, with BLA submission planned for 2026

Del-zota one-year data demonstrated sustained muscle protection leading to meaningful improvement and reversal of disease progression across multiple key functional measures

Strong balance sheet with ~$1.9 billion in cash, cash equivalents, and marketable securities

SAN DIEGO, Nov. 10, 2025 /PRNewswire/ -- Avidity Biosciences, Inc. (Nasdaq: RNA), a biopharmaceutical company committed to delivering a new class of RNA therapeutics called Antibody Oligonucleotide Conjugates (AOCs™) to profoundly improve people's lives, today reported financial results for the third quarter ended September 30, 2025, and highlighted recent progress.

"In October, we announced that Avidity entered into a definitive merger agreement with Novartis, which we believe maximizes value for our investors, accelerates the global reach of our innovative neuroscience pipeline, and advances even more possibilities for our innovative science," said Sarah Boyce, president and chief executive officer of Avidity. "This important transaction, alongside compelling del-zota data and a successful pre-BLA meeting with the FDA in the third quarter, underscores the remarkable consistency of our AOC platform and the significant potential of del-zota, del-desiran, and del-brax to transform outcomes for people living with serious rare diseases. These achievements are possible because of our incredibly talented Avidity team and the close collaboration of the dedicated patient and clinical communities we serve."

Company Announcements, Highlights and Upcoming Milestones

- **Definitive Merger Agreement with Novartis AG**
  - In October 2025, Avidity announced it had entered into a definitive merger agreement with Novartis AG ("Novartis") which was unanimously approved by the Boards of Directors of both Avidity and Novartis. The closing of the acquisition will follow the separation of Avidity's early-stage precision cardiology programs into SpinCo, which is expected to be a publicly traded company. SpinCo will be led by Kathleen Gallagher, currently Avidity's chief program officer, as chief executive officer. Sarah Boyce, currently Avidity's chief executive officer, will serve as chair of the board.
  - Novartis will acquire Avidity's programs and pipeline in neuroscience and gain access to its differentiated RNA-targeting delivery platform, which includes three late-stage clinical development programs: delpacibart zotadirsen (del-zota) for the treatment of Duchenne muscular dystrophy (DMD), delpacibart etedesiran (del-desiran) for the treatment of myotonic dystrophy type 1 (DM1) and delpacibart braxlosiran (del-brax) for the treatment of facioscapulohumeral muscular dystrophy (FSHD).
  - Expected closing is in the first half of 2026, subject to completion of the separation of SpinCo from Avidity and other customary closing conditions.
- **Delpacibart zotadirsen (del-zota) for the treatment of people living with Duchenne muscular dystrophy with mutations amenable to exon 44 skipping (DMD44):**
  - Clear path forward aligned with FDA followingOctober 2025 pre-BLA meeting. The BLA submission is planned for 2026 for accelerated approval.
  - In September 2025, Avidity shared positive topline and functional del-zota data from EXPLORE44® and EXPLORE44-OLE™ trials demonstrating consistent, clinically meaningful improvements across functional endpoints at approximately one year of treatment. Data demonstrated reversal of disease progression and unprecedented improvement compared to baseline and natural history across multiple functional measures. Del-zota continued to demonstrate a favorable long-term safety and tolerability profile.
  - In July 2025, Avidity announced the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to del-zota.
- **Delpacibart etedesiran (del-desiran) for the treatment of myotonic dystrophy type 1 (DM1):**
  - In July 2025, Avidity announced completion of enrollment for the Phase 3 HARBOR™ trial, the first global Ph3 trial of del-desiran for the treatment of DM1.
  - Expected publication of data analyses from the completed Phase 1/2 MARINA® trial in the fourth quarter of 2025.
  - 54-week topline data readout from global Phase 3 HARBOR™ study expected in the second half of 2026.
- **Delpacibart braxlosiran (del-brax) for the treatment of facioscapulohumeral muscular dystrophy(FSHD):**
  - Topline data from FORTITUDE™ biomarker cohort expected in the second quarter of 2026.
  - Alignment with FDA on accelerated and full approval pathways for del-brax, and initiated global, confirmatory Phase 3

study, FORTITUDE-3™, intended to support global approval strategy for del-brax.
- Phase 3 FORTITUDE-3™ readout and global regulatory submissions expected in 2028.

- **Collaboration Progress:**

  - In the third quarter of 2025, Avidity received collaboration revenue of a$10.0 million clinical development milestone under Avidity's research collaboration and license agreement with Eli Lilly and Company.

Third Quarter 2025 Financial Results

- Cash, cash equivalents and marketable securities totaled approximately $1.9 billion as of September 30, 2025, which reflects net proceeds of $651.4 million from a public offering and $185.5 million from the sale of common stock under the Company's sales agreement.

  - The Company expects that its cash, cash equivalents and marketable securities as ofSeptember 30, 2025, will be sufficient to fund its operations to mid-2028.

- Collaboration revenues of $12.5 million for the third quarter of 2025 and $17.9 million for the first nine months of 2025, primarily relate to a $10.0 million clinical development milestone under Avidity's research collaboration and license agreement with Eli Lilly and Company, as well as additional revenues under Avidity's research collaboration and license agreement with Bristol Myers Squibb. Collaboration revenues of $2.3 million for the third quarter of 2024 and $7.9 million for the first nine months of 2024, primarily relate to revenues under Avidity's research collaboration and license agreement with Bristol Myers Squibb.
- Research and development expenses for the third quarter of 2025 were $154.9 million, compared to $77.2 million for the same period of 2024. Research and development expenses for the nine months ended September 30, 2025 were $392.6 million, compared to $208.0 million for the same period of 2024. The increases were primarily driven by increased costs associated with the advancement of del-desiran, del-brax and del-zota, higher manufacturing costs, and higher personnel costs.
- General and administrative expenses for the third quarter of 2025 were $46.3 million, compared to $23.3 million for the same period of 2024. General and administrative expenses for the nine months ended September 30, 2025 were $116.8 million, compared to $57.9 million for the same period of 2024. The increases were primarily due to higher personnel and commercial infrastructure costs to support the company's expanded operations.

About Avidity
Avidity Biosciences, Inc.'s mission is to profoundly improve people's lives by delivering a new class of RNA therapeutics - Antibody Oligonucleotide Conjugates (AOCs™). Avidity is revolutionizing the field of RNA with its proprietary AOCs, which are designed to combine the specificity of monoclonal antibodies with the precision of oligonucleotide therapies to address targets and diseases previously unreachable with existing RNA therapies. Utilizing its proprietary AOC platform, Avidity demonstrated the first-ever successful targeted delivery of RNA into muscle and is leading the field with clinical development programs for three rare muscle diseases: DM1, DMD and FSHD. Avidity is also advancing two wholly-owned precision cardiology development candidates addressing rare genetic cardiomyopathies. In addition, Avidity is broadening the reach of AOCs with its advancing and expanding pipeline including programs in cardiology and immunology through key partnerships. Avidity is headquartered in San Diego, CA. For more information about our AOC platform, clinical development pipeline and people, please visit www.aviditybiosciences.com and engage with us on LinkedIn and X.

Additional Information and Where to Find It
In connection with the spin-off and the merger (the "Transactions"), Novartis, Avidity and SpinCo intend to file relevant documents with the Securities and Exchange Commission (the "SEC"), including a preliminary and definitive proxy statement to be filed by Avidity. The definitive proxy statement and proxy card will be delivered to the stockholders of Avidity in advance of the special meeting relating to the Transactions. This document is not a substitute for the proxy statement or any other document that may be filed by Avidity with the SEC. AVIDITY'S STOCKHOLDERS ARE URGED TO READ THE DEFINITIVE PROXY STATEMENT IN ITS ENTIRETY WHEN IT BECOMES AVAILABLE AND ANY OTHER DOCUMENTS FILED BY EACH OF NOVARTIS AND AVIDITY WITH THE SEC IN CONNECTION WITH THE TRANSACTIONS OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTIONS AND THE PARTIES TO THE PROPOSED TRANSACTIONS. Investors and security holders will be able to obtain a free copy of the proxy statement and such other documents containing important information about Novartis and Avidity, once such documents are filed with the SEC, through the website maintained by the SEC at www.sec.gov. Novartis and Avidity make available free of charge at the Novartis website at www.novartis.com/investors/financial-data/sec-filings and Avidity's website at investors.aviditybiosciences.com/sec-filings, respectively, copies of documents they file with, or furnish to, the SEC. The contents of the websites referenced above will not be deemed to be incorporated by reference into the proxy statement.

Participants in the Solicitation
This communication does not constitute a solicitation of a proxy. Novartis, Avidity and their respective directors, executive officers and certain employees may be deemed to be participants in the solicitation of proxies from the stockholders of Avidity in connection with the Transactions. Information regarding the special interests of these directors and executive officers in the Transactions will be included in the definitive proxy statement referred to above. Security holders may also obtain information regarding the names, affiliations and interests of the Novartis directors and executive officers in the Novartis Annual Report on Form 20-F for the fiscal year ended December 31, 2024, which was filed with the SEC onJanuary 31, 2025. Security holders may obtain information regarding the names, affiliations and interests of Avidity's directors and executive officers in Avidity's definitive proxy statement on Schedule 14A, which was filed with the SEC on April 29, 2025. To the extent the holdings of Avidity's securities by Avidity's directors and executive officers have changed since the amounts set forth in Avidity's definitive proxy statement for its 2025 annual meeting of stockholders,

such changes have been reflected in the following Statements of Change in Ownership on Form 4 filed with the SEC: by Eric Mosbrooker, dated October 7, 2025, September 5, 2025 and August 8, 2025; by Steven Hughes, dated October 24, 2025, September 23, 2025, September 17, 2025, August 22, 2025, August 15, 2025 and August 8, 2025; by Teresa McCarthy, dated October 15, 2025, September 17, 2025 and August 15, 2025; by Michael Flanagan, dated September 12, 2025 and June 12, 2025; by Troy Wilson, dated September 9, 2025, August 8, 2025 and June 12, 2025; by Sarah Boyce, dated September 5, 2025 and August 29, 2025; by Kathleen Gallagher, dated September 2, 2025, June 18, 2025, June 4, 2025 and May 2, 2025; by Michael MacLean, dated August 15, 2025; by Arthur Levin, dated August 8, 2025 and June 12, 2025; by John Moriarty, dated August 5, 2025; by Noreen Henig, dated June 12, 2025; by Carsten Boess, dated June 12, 2025; by Edward Kaye, dated June 12, 2025; by Simona Skerjanec, dated June 12, 2025; by Tamar Thompson, dated June 12, 2025; and by Jean Kim, dated June 12, 2025. These documents (when available) may be obtained free of charge from the SEC's website at www.sec.gov, the Novartis website atwww.novartis.com/investors/financial-data/sec-filings and Avidity's website at investors.aviditybiosciences.com/sec-filings. The contents of the websites referenced above are not deemed to be incorporated by reference into the proxy statement.

No Offer or Solicitation
This communication is for informational purposes only and is not intended to and does not constitute, or form part of, an offer, invitation or the solicitation of an offer or invitation to purchase, otherwise acquire, subscribe for, sell or otherwise dispose of any securities, or the solicitation of any vote or approval in any jurisdiction, pursuant to the proposed transaction or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law.

Forward-Looking Statements
This communication contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "may," "could," "would," "expect," "anticipate," "look forward," "believe," "committed," "investigational," "pipeline," "launch," or similar terms, or by express or implied discussions regarding the proposed acquisition of Avidity and Avidity's related spin-off, the expected timetable for completing each of the proposed Transactions, the composition of the assets and liabilities to be held by SpinCo and Avidity following the spin-off, the management team for SpinCo and its cash balance, potential marketing approvals, new indications or labeling for Avidity's product candidates, Avidity's platform and preclinical assets, or potential future revenues from Avidity's product candidates. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that Avidity's investigational products will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time, or that Avidity's approach to the discovery and development of product candidates based on its AOC™ platform will produce any products of commercial value. There can be no guarantee that the conditions to the closing of the Transactions will be satisfied on the expected timetable or at all or that the expected benefits or synergies from the Transactions will be achieved in the expected timeframe, or at all. In particular, expectations regarding Avidity, SpinCo, or the Transactions could be affected by, among other things, the timing of the satisfaction of customary closing conditions, including the receipt of regulatory approvals and the approval of Avidity's stockholders, on acceptable terms or at all; risks and costs related to the implementation of the separation of SpinCo, including the ability to complete the separation in the anticipated timeframe, or at all, and any changes to the configuration of the businesses included in the separation if implemented; the sale of certain of SpinCo's assets pursuant to a third party right of first negotiation; the risk that competing offers or acquisition proposals will be made; the effects of disruption from the Transactions and the impact of the announcement and pendency of the Transactions on Novartis' and/or Avidity's businesses, including their relationships with employees, business partners or governmental entities; the risk that the Transactions may be more expensive to complete than anticipated; the risk that stockholder litigation in connection with the Transactions may result in significant costs of defense, indemnification and liability; a diversion of management's attention from ongoing business operations and opportunities as a result of the Transactions or otherwise; the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; and the risks and factors referred to in Novartis AG's most recent Annual Report on Form 20-F for the year ended December 31, 2024, Avidity's Annual Report on Form 10-K for the year endedDecember 31, 2024 and Quarterly Reports on Form 10-Q for the quarters ended March 31, 2025 and June 30, 2025, and any subsequent filings made by either party with the SEC, available on the SEC's website at www.sec.gov, Avidity is providing the information in this communication as of this date and does not undertake any obligation to update any forward-looking statements contained in this communication as a result of new information, future events or otherwise, except to the extent required by law.

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Avidity Biosciences, Inc.
Selected Condensed Consolidated Financial Information
(in thousands, except per share data)
(unaudited)

Statements of Operations	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Collaboration revenue	$ 12,475	$ 2,336	$ 17,895	$ 7,924
Operating expenses:				
Research and development	154,948	77,197	392,563	207,968
General and administrative	46,333	23,273	116,797	57,902
Total operating expenses	201,281	100,470	509,360	265,870
Loss from operations	(188,806)	(98,134)	(491,465)	(257,946)
Other income, net	14,364	17,736	43,935	37,901
Net loss	$ (174,442)	$ (80,398)	$ (447,530)	$ (220,045)
Net loss per share, basic and diluted	$ (1.27)	$ (0.65)	$ (3.38)	$ (2.08)
Weighted-average shares outstanding, basic and diluted	137,895	123,375	132,281	105,902

Balance Sheets	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 350,158	$ 219,868
Marketable securities	1,525,678	1,281,629
Prepaid and other current assets	90,181	40,793
Total current assets	1,966,017	1,542,290
Property and equipment, net	21,504	12,670
Restricted cash	2,798	2,795
Right-of-use assets	52,848	5,619
Other assets	91,042	521
Total assets	$ 2,134,209	$ 1,563,895
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and other liabilities	$ 150,756	$ 77,031
Deferred revenue, current portion	19,123	20,987
Total current liabilities	169,879	98,018
Lease liabilities, net of current portion	45,999	2,957
Deferred revenue, net of current portion	32,066	37,961
Total liabilities	247,944	138,936
Stockholders' equity	1,886,265	1,424,959
Total liabilities and stockholders' equity	$ 2,134,209	$ 1,563,895

SOURCE Avidity Biosciences, Inc.

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https://investors.aviditybiosciences.com/2025-11-10-Avidity-Biosciences-Reports-Third-Quarter-2025-Financial-Results-and-Recent-Highlights