

# Amicus Therapeutics and ARYA Sciences Acquisition Corp IV Announce Formation of a Next-Generation Genetic Medicine Company: "Caritas Therapeutics"

September 29, 2021

Business Combination of Amicus Gene Therapy Business with ARYA IV to Result in the Launch of Caritas Therapeutics, a New Independent, Publicly Traded Company with Expected ~\$400M in Initial Funding

Will Transform Amicus into a Premier Global Commercialization and Late Stage Product Development Biotechnology Company in Rare
Diseases

Transaction Advances Amicus Path to Profitability - Expected as of 2023

Amicus Balance Sheet Further Strengthened with a ~\$200M Private Investment from Leading Biotechnology Investors

Separation will Sharpen the Strategic Focus, Financial Profile, and Operational Execution of Both Companies to Address the Needs of People Living with Rare Diseases – Amicus to Retain Ownership of 36% of Caritas

#### Conference Call and Webcast Today at 8:00 a.m. ET

PHILADELPHIA & NEW YORK, Sept. 29, 2021 (GLOBE NEWSWIRE) -- Amicus Therapeutics, Inc. (Nasdaq: FOLD) ("Amicus") today announced its intent to launch a next-generation genetic medicine company, Caritas Therapeutics, Inc., ("Caritas") through a definitive business combination agreement pursuant to which the Amicus gene therapy business will be acquired by ARYA Sciences Acquisition Corp IV (Nasdaq: ARYD) ("ARYA IV"), a special purpose acquisition company or SPAC, sponsored by Perceptive Advisors. The transaction will result in two independent publicly traded companies with attractive stand-alone investment profiles. Amicus will become the largest shareholder in Caritas with a ~36% ownership stake (assuming no redemptions by ARYA's shareholders) and retain co-development and commercialization rights to the Fabry and Pompe gene therapy programs as well as negotiation rights on select future muscular dystrophy programs.

Upon consummation of the business combination, current Amicus Chairman and Chief Executive Officer John F. Crowley will lead Caritas as Chairman and Chief Executive Officer and will become the Chairman Emeritus and Chief Strategic Advisor for Amicus. Current Amicus President and Chief Operating Officer Bradley Campbell will be named as Chief Executive Officer of Amicus.

"This is a big, bold vision and a massive step forward for next generation biotechnologies for people worldwide living with some of the most devastating rare diseases. In a single stroke with the formation and funding of Caritas we will create what will be one of the world's preeminent next-generation genetic medicines companies. We strongly believe that separating our business into two highly focused, stand-alone companies is the best way to unlock significant value for Amicus shareholders and to advance our medicines and technologies to people living with rare diseases around the world," stated John F. Crowley, Chairman and Chief Executive Officer of Amicus. "This transaction will serve patients and shareholders well by accelerating funding for our next generation gene therapy pipeline, and strengthening the financial profiles of both companies. We are immensely excited for what the future of science and biotechnology holds as we accelerate and recommit to our mission."

"This transaction will transform Amicus into a premier rare disease global commercialization and late stage product development company that we believe will benefit all of our stakeholders," said Bradley Campbell, President and Chief Operating Officer of Amicus. "The separation strengthens the financial profile of Amicus and accelerates our path to profitability, while preserving significant equity ownership in the gene therapy pipeline and commercial rights to the innovative and important Fabry and Pompe gene therapy programs. We will be laser focused on maintaining the growth of Galafold and executing on the anticipated global launch of AT-GAA, as we build Amicus into a leading global rare disease biotechnology company and bring our medicines to as many patients as quickly as possible."

Amicus expects the separation to create value for all stakeholders and result in material benefits to the stand-alone companies, including:

- Enhancing the ability of both companies to meet the unmet needs of many individuals and families affected by rare diseases,
- Accelerating the development and broadening the scope of one of the largest rare disease gene therapy portfolios in the industry,
- Funding the gene therapy next generation scientific platform technologies as well as manufacturing capabilities of the new company,
- Strengthening the financial profile of each company,
- Reinforcing management focus on key strategic and financial goals,
- Unlocking value while creating a more targeted investment thesis for shareholders.

# Amicus Therapeutics' focus as a rare disease global commercialization and late stage development company

Following the transaction, Amicus will remain a global, patient-dedicated biotechnology company developing and delivering novel high-quality medicines for people living with rare diseases. Amicus' focus will be to grow its leadership position across Amicus' two lead indications of Fabry disease and Pompe disease. In addition, it is expected the transaction will strengthen the Amicus financial outlook and enable it to achieve profitability in 2023.<sup>1</sup>

Upon completion of the transaction, Amicus will become the largest shareholder in Caritas and retain co-development and commercialization rights to the Fabry and Pompe gene therapy programs, as well as negotiation rights on future muscular dystrophy programs.

Amicus plans to continue investing in the global commercialization of Galafold for Fabry disease through geographic and label expansion, as well as support for diagnostic initiatives. In Pompe disease, Amicus will focus on securing global approvals, executing the anticipated global launch of AT-GAA, and providing access for patients as quickly as possible. Amicus continues to believe that AT-GAA has the potential upon approval to become the next standard of care for all people living with Pompe disease.

Amicus also announced today that a syndicate of leading healthcare biotechnology investors, including Redmile Group, Avoro Capital Advisors, Perceptive Advisors, Invus, Sphera Healthcare, and Janus Henderson Investors have agreed to a private investment in Amicus of approximately \$200 million. Amicus expects to use the net proceeds to further fund initiatives in the global commercialization of Galafold and the anticipated global launch of AT-GAA and, in connection with the business combination, to invest \$50 million in cash in Caritas in exchange for additional equity.

<sup>1</sup> Based on projections of Amicus non-GAAP Net Income under current operating plans, which includes successful AT-GAA regulatory approvals and continued Galafold growth. We define non-GAAP Net Income as GAAP Net Income excluding the after tax impact of share-based compensation expense, changes in fair value of contingent consideration and depreciation.

## Caritas' focus as a clinical stage, rare disease discovery and development next-generation genetic medicines company

The mission of Caritas, the Latin word for compassion, will be to transform the lives of children and adults living with rare genetic diseases by harnessing the power of next-generation genetic medicine and gene therapy technologies through advanced protein engineering and innovative gene therapy vector technologies. Through its 60+ bench scientists and experienced development and leadership teams, Caritas will develop and advance a series of novel platform technologies to address the key challenges to the safe and efficient gene transfer necessary for next-generation gene therapies. These include proprietary technologies designed to address delivery, safety, durability, and manufacturability of gene therapies. The gene therapy pipeline is founded on deep expertise and platform technologies in protein engineering and rare disease biology, the broad research collaboration with the Perelman School of Medicine at the University of Pennsylvania (Penn) for best-in-class gene therapies, and a new co-development collaboration with Amicus.

The pipeline is led by two Batten disease programs with clinical proof of concept in CLN6 and CLN3, six active preclinical programs, including Fabry disease, Pompe disease, and CDKL5 Deficiency Disorder (CDD), as well as multiple discovery programs. Caritas will have exclusive, global rights to gene therapy programs for nearly 50 rare genetic diseases through its broad collaboration with Dr. Jim Wilson and the Penn team, including a majority of next-generation lysosomal disease programs as well as 11 more prevalent rare diseases. Among these are Angelman Syndrome, Duchenne Muscular Dystrophy, Rett Syndrome, Myotonic Dystrophy and select other muscular dystrophies. Dr. Jim Wilson will become a senior scientific and strategic advisor to Caritas.

Amicus management expects that, as a new, independent entity with approximately 115 employees, Caritas will be better positioned to pursue its strategic priorities, accelerate its programs and discovery work, as well as adequately fund its manufacturing capabilities. Amicus believes that this transaction will harness those opportunities to the benefit of patients and shareholders.

"When ARYA IV was formed, our objective was to identify a company with the potential to successfully address a significant, unmet need in biomedical science," said Adam Stone, Chief Investment Officer of Perceptive Advisors and CEO of ARYA IV. "Through Caritas, we are combining with a business we believe has the potential to transform the field of genetic medicine through advanced protein engineering and innovative vector technologies. Over the course of our long-standing relationship with Amicus, we've come to believe in the company's innovative science and experienced leadership team. We are excited to see the next phase of growth for Amicus and Caritas, respectively."

#### **Caritas Transaction and Timing**

Amicus is separating its gene therapy business into a new entity that will be acquired by ARYA IV, a special purpose acquisition company or SPAC. At closing of the transaction, ARYA IV will be named Caritas Therapeutics, Inc. As part of the transaction, Amicus will receive the following:

- ~36% pro forma ownership in Caritas (depending on the level of redemptions at ARYA IV)
- Co-development rights and exclusive global commercialization rights to existing Fabry and Pompe gene therapies including a 50/50 cost and profit share
- Right of first negotiation to certain multiple muscular dystrophy programs being developed by Caritas

Amicus expects to incur charges related to the transaction during the reporting periods preceding the separation and does not otherwise expect this to impact Amicus' financial guidance for 2021.

In connection with the closing of the transaction, in addition to its renaming, ARYA IV will redomicile as a Delaware corporation and its common stock is expected to be listed on Nasdaq under the ticker symbol "SPES", the Latin word for hope.

In addition to the approximately \$150 million held in ARYA Ms trust account, assuming no redemptions are effected, a group of leading global investors has committed to participate in the transaction through a common stock private investment in public equity (PIPE) of approximately \$200 million at \$10 per share. Investors in the PIPE include Perceptive Advisors, Redmile Group, Bain Capital Life Sciences, Invus, Avoro Capital Advisors, Surveyor Capital (a Citadel company), Deerfield Management Company, Wellington Management and Sphera Healthcare. In connection with the business combination, Amicus will also invest \$50 million in cash in Caritas in exchange for additional equity in Caritas. Together, Caritas is expected to receive proceeds of approximately \$400 million at the closing of the transactions, assuming no redemptions are effected. Proceeds of the business combination and the PIPE are expected to be used to advance development of the Caritas gene therapy pipeline, discovery work, growth across its scientific teams and to support general corporate activities (including payment of certain transaction expenses). A condition to closing of the business combination transaction is that these cash proceeds are no less than \$300 million in total.

The boards of directors of both Amicus and ARYA IV have approved the proposed transaction. Completion of the transaction, which is expected in the fourth quarter of 2021 or early 2022, is subject to approval of ARYA IV's shareholders, delivery of the minimum \$300 million in cash proceeds, and the satisfaction or waiver of certain other customary closing conditions.

#### **Advisors**

Goldman Sachs & Co. LLC is acting as financial and capital markets advisor to Amicus Therapeutics. Jefferies LLC is acting as financial advisor and private placement agent to ARYA IV. Skadden, Arps, Slate, Meagher & Flom LLP, Wilson Sonsini Goodrich & Rosati and Troutman Pepper Hamilton Sanders LLP are acting as legal counsel to Amicus Therapeutics. Kirkland & Ellis LLP is acting as legal counsel to ARYA IV.

#### **Amicus Conference Call and Webcast**

Amicus Therapeutics will host a conference call and audio webcast today, September 29, 2021 at 8:00 a.m. ET to discuss the transaction. Interested participants and investors may access the conference call by dialing 877-303-5859 (U.S./Canada) or 678-224-7784 (international), conference ID: 4688658.

A live audio webcast and related presentation materials can also be accessed via the Investors section of the Amicus Therapeutics corporate website at ir.amicusrx.com. Web participants are encouraged to register on the website 15 minutes prior to the start of the call. A replay of the call will be available for seven days beginning at 7:30 p.m. ET on September 29, 2021. Access numbers for this replay are 855-859-2056 (U.S./Canada) and 404-537-3406 (international); conference ID: 4688658.

#### **Caritas Deal Roadshow Webcast**

A webcast of the Caritas Therapeutics presentation materials will also be available on Deal Roadshow:

## Recorded Deal Roadshow Investor Login Details:

Wednesday, September 29, 2021 at 9:00 a.m. ET

URL: <a href="https://dealroadshow.com">https://dealroadshow.com</a>
Entry Code: CARITAS2021

Direct Link: https://dealroadshow.com/e/CARITAS2021

A replay of the call will be available today starting at 10:00 a.m. ET through the same Deal Roadshow link shown above.

## **About Amicus Therapeutics**

Amicus Therapeutics (Nasdaq: FOLD) is a global, patient-dedicated biotechnology company focused on discovering, developing and delivering novel high-quality medicines for people living with rare diseases. With extraordinary patient focus, Amicus Therapeutics is committed to advancing and expanding a robust pipeline of cutting-edge, first- or best-in-class medicines for rare metabolic diseases. For more information please visit the company's website at <a href="https://www.amicusrx.com">www.amicusrx.com</a>, and follow us on <a href="https://www.amicusrx.com">Twitter</a> and <a href="https://www.amicusrx.com">LinkedIn</a>.

#### **About ARYA IV**

ARYA IV is a blank check company newly incorporated as a Cayman Islands exempted company for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses or entities. ARYA IV is led by Chairman Joseph Edelman; Chief Executive Officer Adam Stone; Chief Financial Officer Michael Altman; and Chief Business Officer Konstantin Poukalov.

# Participants in the Solicitation

ARYA IV and its directors, executive officers, other members of management, and employees, under SEC rules, may be deemed to be participants in the solicitation of proxies of ARYA IV's shareholders in connection with the business combination. Investors and securityholders may obtain more detailed information regarding the names and interests in the business combination of ARYA IV's directors and officers in ARYA IV's filings with the SEC, including ARYA IV's final prospectus which was filed with the SEC pursuant to Rule 424(b) of the Securities Act of 1933, as amended (the "Securities Act") on February 19, 2021, as well as in the Registration Statement, which includes the proxy statement of ARYA IV for the business combination. Shareholders can obtain copies of ARYA IV's filings with the SEC, without charge, at the SEC's website at <a href="https://www.sec.gov">www.sec.gov</a>.

## **Forward Looking Statement**

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to the business combination, development of Caritas' product candidates, preclinical and clinical development of our product candidates, the timing and reporting of results from preclinical studies and clinical trials, the prospects and timing of the potential regulatory approval of our product candidates, commercialization plans, manufacturing plans and financing plans. The inclusion of forward-looking statements should not be regarded as a representation by us that any of our plans or Caritas' plans will be achieved. Any or all of the forward-looking statements in this press release may turn out to be wrong and can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. For example, with respect to statements regarding the goals, progress, timing, and outcomes of discussions with regulatory authorities, and in particular the potential goals, progress, timing, and results of preclinical studies and clinical trials, and revenue goals, including as they are impacted by COVID-19 related disruption, are based on current information. The potential impact on operations and/or revenue from the COVID-19 pandemic is inherently unknown and cannot be predicted with confidence and may cause actual results and performance to differ materially from the statements in this release, including without limitation, because of the impact on general political and economic conditions, including as a result of efforts by governmental authorities to mitigate COVID-19, such as travel bans, shelter in place orders and third-party business closures and resource allocations, manufacturing and supply chain disruptions and limitations on patient access to commercial or clinical product or to treatment sites. In addition to the impact of the COVID-19 pandemic, actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in our business, including, without limitation: the potential that the transaction may not be completed in a timely manner or at all, which may adversely affect the price of our securities; the potential that the proposed transaction disrupts our current plans and operations and potential difficulties in our employee retention as a result of the transaction; the potential that results of clinical or preclinical studies indicate that the product candidates are unsafe or ineffective; the potential that it may be difficult to enroll patients in clinical trials; the potential that regulatory authorities, including the FDA, EMA, and PMDA, may not grant or may delay approval for our product candidates; the potential that Caritas may not be successful in maintaining or establishing collaborations, which could adversely affect its ability to develop products; substantial competition in the rapidly evolving field of gene therapy, which may result in others discovering, developing or commercializing products before or more successfully than Caritas; the potential that regulatory authorities approve biosimilar products with claims that compete with any of Caritas' product candidates: the potential that preclinical and clinical studies could be delayed due to the identification of serious side effects or other safety issues; the potential that we or Caritas may not be able to manufacture or supply sufficient clinical or commercial products; the potential that Caritas may become involved in product liability lawsuits and in lawsuits to protect or enforce intellectual property rights, which could be expensive and time-consuming, and could result in substantial liabilities and the impairment of commercialization efforts of product candidates; and the potential that we or Caritas will need additional funding to complete all of our respective studies, commercialization and manufacturing. In addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2020 and Quarterly Report 10-Q for the quarter ended June 30, 2021. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update this news release to reflect events or circumstances after the date hereof.

# No Offer or Solicitation

This press release is for informational purposes only and is neither an offer to purchase, nor a solicitation of an offer to sell, subscribe for or buy any securities or the solicitation of any vote in any jurisdiction pursuant to the business combination or otherwise, nor shall there be any sale, issuance or transfer or securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act and otherwise in accordance with applicable law.

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