

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): September 28, 2022

Idera Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State of other jurisdiction of incorporation)

001-31918
(Commission
File Number)

04-1187261
(I.R.S. Employer
Identification No.)

505 Eagleview Blvd., Suite 212
Exton, Pennsylvania 19341
(Address of principal executive offices)

Registrant's telephone number, including area code (484) 348-1600

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions :

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---------------------------------|----------------------|--|
| Common stock, \$0.001 Par Value | IDRA | Nasdaq Capital Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

On September 28, 2022, Idera Pharmaceuticals, Inc., a Delaware corporation (“Idera”), and Aceragen, Inc., a Delaware corporation (“Aceragen”), issued a joint press release (the “Press Release”) announcing that Idera had acquired Aceragen, pursuant to an Agreement and Plan of Merger, dated September 28, 2022, by and among Idera, Bell Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of Idera, Bell Merger Sub II, LLC, a Delaware limited liability company and wholly owned subsidiary of Idera (the “Merger”), and Aceragen, and that Idera will hold an investor conference call to discuss the Merger today, September 28th, at 5:00 p.m. Eastern time. A webcast of the investor conference will be broadcast live from approximately 5:00 p.m. to 6:00 p.m. Eastern time and will be accessible via Idera’s corporate website at ir.iderapharma.com.

Also on September 28, 2022, Idera made available on its corporate website the slide presentation to be used during today’s investor conference to discuss the Merger. Copies of the Press Release and the slide presentation are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K, and are incorporated herein by reference. The information in Exhibit 99.1 and Exhibit 99.2 is presented as of the particular date or dates referenced therein, and except as may be required by applicable law, Idera does not undertake any obligation to, and disclaims any duty to, update or revise any of the information provided therein.

The information in Item 7.01 of this Current Report on Form 8-K, including the information in the Press Release attached as Exhibit 99.1 and in the slide presentation attached as Exhibit 99.2 to this Current Report on Form 8-K, is furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. Furthermore, the information in Item 7.01 of this Current Report on Form 8-K, including the information in the Press Release attached as Exhibit 99.1 and in the slide presentation attached as Exhibit 99.2 to this Current Report on Form 8-K, shall not be deemed to be incorporated by reference in the filings of Idera under the Securities Act of 1933, as amended.

Website addresses are included as inactive textual references only. The information contained on the websites referenced herein is not incorporated into this Current Report on Form 8-K.

Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding: uses of proceeds; projected cash runways; future product development plans; and stockholder approval of the conversion rights of the Series Z Preferred Stock. The use of words such as, but not limited to, “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” and similar words expressions are intended to identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on Idera’s current beliefs, expectations and assumptions regarding the future of its business, future plans and strategies, clinical results and other future conditions. There are a number of important factors that could cause Idera’s actual results to differ materially from those indicated or implied by such forward-looking statements including, without limitation: whether Idera will be able to successfully integrate the Aceragen operations and realize the anticipated benefits of the acquisition of Aceragen; whether Idera is able to resolve the clinical hold affecting the ACG 801 program; whether Idera’s stockholders approve the conversion of the Series Z Preferred Stock; whether Idera’s cash resources will be sufficient to fund Idera’s continuing operations and the newly acquired Aceragen operations, including the liabilities of Aceragen incurred in connection with the completion of the Merger; whether Idera’s products will advance into or through the clinical trial process when anticipated or at all or warrant submission for regulatory approval; whether such products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; whether, if Idera’s products receive approval, they will be successfully distributed and marketed; whether Idera’s collaborations will be successful; and whether Idera will be able to comply with the continued listing requirements of the Nasdaq Capital Market. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. Idera may not actually achieve the forecasts disclosed in such forward-looking statements, and you should not place undue reliance on such forward-looking statements. Such forward-looking statements are subject to a number of material risks and uncertainties including but not limited to those set forth under the caption “Risk Factors” in Idera’s most recent Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in its subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Neither Idera, nor any of its affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing Idera’s views as of any date subsequent to the date hereof.

Important Additional Information and Where to Find It

Idera Pharmaceuticals, Inc., its directors and certain of its executive officers are deemed to be participants in the solicitation of proxies from Idera Pharmaceuticals' stockholders in connection with the matters to be considered at Idera Pharmaceuticals 2022 Special Meeting of Stockholders. Information regarding the names of Idera Pharmaceuticals' directors and executive officers and their respective interests in Idera Pharmaceuticals by security holdings or otherwise can be found in Idera Pharmaceuticals' proxy statement for its 2022 Annual Meeting of Stockholders, filed with the SEC on [April 29, 2022](#). To the extent holdings of Idera Pharmaceuticals' securities have changed since the amounts set forth in Idera Pharmaceuticals' proxy statement for the 2022 Annual Meeting of Stockholders, such changes have been reflected on Initial Statements of Beneficial Ownership on Form 3 or Statements of Change in Ownership on Form 4 filed with the SEC. These documents are available free of charge at the SEC's website at www.sec.gov. Idera Pharmaceuticals intends to file a proxy statement and accompanying proxy card with the SEC in connection with the solicitation of proxies from Idera Pharmaceuticals stockholders in connection with the matters to be considered at Idera Pharmaceuticals' 2022 Special Meeting of Stockholders. Additional information regarding the identity of participants, and their direct or indirect interests, by security holdings or otherwise, will be set forth in Idera Pharmaceuticals' proxy statement for its 2022 Special Meeting, including the schedules and appendices thereto. **INVESTORS AND STOCKHOLDERS ARE STRONGLY ENCOURAGED TO READ ANY SUCH PROXY STATEMENT AND THE ACCOMPANYING PROXY CARD AND ANY AMENDMENTS AND SUPPLEMENTS THERETO AS WELL AS ANY OTHER DOCUMENTS FILED BY IDERA PHARMACEUTICALS WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE AS THEY WILL CONTAIN IMPORTANT INFORMATION.** Stockholders will be able to obtain copies of the proxy statement, any amendments or supplements to the proxy statement, the accompanying proxy card, and other documents filed by Idera Pharmaceuticals with the SEC for no charge at the SEC's website at www.sec.gov. Copies will also be available at no charge at the Investor Relations section of Idera Pharmaceuticals' corporate website at <https://ir.iderapharma.com/> or by contacting Idera Pharmaceuticals' Investor Relations at Idera Pharmaceuticals, Inc., 505 Eagleview Blvd., Suite 212 Exton, Pennsylvania 19341 or by calling Idera Pharmaceuticals' Investor Relations at (877) 888-6550.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

| Exhibit Number | Description |
|----------------------|---|
| 99.1 | Joint Press Release of Idera Pharmaceuticals, Inc. and Aceragen, Inc., dated September 28, 2022 |
| 99.2 | Slide presentation dated September 28, 2022. |
| Exhibit 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 28, 2022

IDERA PHARMACEUTICALS, INC.

By: /s/ Bryant D. Lim
Bryant D. Lim
Chief Business Officer and General Counsel



Idera Pharmaceuticals Acquires Aceragen

Acquisition includes late-stage rare disease portfolio with anticipated 2023 clinical milestones and first potential product approval as early as late 2024

Conference call and webcast today at 5:00 p.m. ET

EXTON, PA and DURHAM, NC, September 28, 2022 — Idera Pharmaceuticals, Inc. (“Idera,” the “Company,” “we,” “us,” or “our”) (Nasdaq: IDRA) today announced it has completed the acquisition of Aceragen, Inc. (“Aceragen”), a privately-held biotechnology company addressing rare, orphan pulmonary and rheumatic diseases for which there are limited or no available treatments. The combined cash of the two companies is expected to provide runway into Q3 2023, funding the advancement of Aceragen’s pipeline, including ACG-701 and ACG-801, through important 2023 clinical milestones. The Company estimates annual peak sales potential of \$650 million from the three current lead programs.

About ACG-701 for Cystic Fibrosis and Melioidosis

ACG-701 is a proprietary formulation of sodium fusidate being developed as a potential treatment for acute pulmonary exacerbations (“PEX”) associated with cystic fibrosis (“CF”) and for melioidosis, a life-threatening infection caused by the *B. pseudomallei* pathogen.

The Phase 2 trial of ACG-701 in CF PEX (the REPRIEVE study) is expected to begin in Q4 2022 and is funded in part by an award from the Cystic Fibrosis Foundation. If approved, ACG-701 would represent the first product in the United States indicated for the treatment of CF PEX, a major factor behind lung function decline in patients living with CF. Data from the REPRIEVE study is expected in Q2 2023. The active component of ACG-701, sodium fusidate, has never been approved in the United States, but has been used for 50+ years with an established clinical efficacy and safety profile ex-US, including as part of CF PEX treatment guidelines in the United Kingdom and Australia. The FDA has assigned Orphan, Fast Track, and Qualified Infectious Disease Product status to ACG-701 for CF PEX.

The melioidosis clinical program for ACG-701 is supported by \$51 million in funding from the Defense Threat Reduction Agency (“DTRA”) due to its potential use as a medical countermeasure. This trial, the TERRA study ([NCT05105035](#)), is underway and is targeting an interim analysis in Q1 2023; complete Phase 2 data is expected in Q2 2023. If approved for this indication, ACG-701 is anticipated to be eligible for a priority review voucher (“PRV”) and a national stockpiling contract.

About ACG-801 for Farber Disease

ACG-801, recombinant human acid ceramidase, is an investigational biologic enzyme replacement therapy being developed for the treatment of Farber disease, a lysosomal storage disorder and progressive rare disease with profound morbidity and often premature death. Acid ceramidase acts in the lysosome to metabolize ceramide, a pro-inflammatory lipid. Loss of acid ceramidase function leads to abnormal accumulation of ceramide, causing macrophage-driven inflammation and multi-organ disease affecting bone, cartilage, the immune system, central nervous system, and the lungs. There are no Farber disease-specific treatments currently available that can alter the natural history of the disease.

The Company expects to initiate the ADVANCE clinical study for ACG-801 in Farber disease in Q1 2023 with data expected in Q1 2024. Due to the ultra-rare nature of Farber disease, this study has the potential to be registrational. The FDA has granted Orphan, Fast Track, and Rare Pediatric Disease designations for ACG-801, which is also anticipated to be eligible for a PRV.

“After a thorough evaluation of strategic alternatives, we and our Board of Directors believe this acquisition represents the highest potential value creation opportunity for Idera’s stockholders,” said Vincent Milano, Idera’s former Chief Executive Officer and newly appointed Chair of the Board. “We are excited by the potential for Aceragen’s rare disease portfolio to result in meaningful therapeutic options for patients, and I am looking forward to being part of this new stage of Idera’s journey.”

Added John Taylor, Idera’s newly appointed Chief Executive, “This is an important transition for Aceragen. We are delighted to complement Aceragen’s exciting rare disease programs and dedicated team with financial resources, corporate structure, and people from Idera, better enabling us to deliver important therapies for patients living with rare diseases.”

Management and Organization

Vincent Milano, Idera’s former Chief Executive Officer, has been named Chair of the Board of Directors for the Company. He has been succeeded by John Taylor, the former Chief Executive Officer of Aceragen. Additional management team members of the combined Company include John Kirby, who will continue in his role as Idera’s Chief Financial Officer; Carl Kraus, Aceragen’s former Chief Medical Officer, who will serve in that role for Idera; Bryant Lim, who will continue in his role as Idera’s Chief Business Officer and General Counsel; Daniel Salain, Aceragen’s former Chief Operating Officer, who will serve in that role for Idera; and Andy Jordan, Aceragen’s former Chief Financial Officer, who has been appointed Chief Strategy Officer for Idera.

In conjunction with the transaction and with the appointment of Vincent Milano as Chair of the Board of Directors, Michael Dougherty, Idera’s former Chair of the Board, will remain an independent Board member of the combined company. Additional Board members include current Idera Board members Cristina Csimma, Pharm. D., M.H.P., James Geraghty, and Maxine Gowen, Ph.D., along with John Taylor and Ron Wooten, Founder and Managing Partner, NovaQuest Capital Management LLC. Mr. Taylor and Mr. Wooten previously served on Aceragen’s board.

About the Transaction

The acquisition of Aceragen was structured as a stock-for-stock transaction whereby all Aceragen outstanding equity interests were exchanged for a combination of shares of Idera common stock, shares of newly designated convertible Series Z preferred stock, and shares of the newly designated Series X preferred stock. Subject to stockholder approval of the conversion and an increase in authorized shares, each share of Series Z preferred stock will automatically convert into 1,000 shares of common stock, subject to certain beneficial ownership limitations set by each holder. Holders of Series X preferred stock are entitled to receive distributions on shares of Series X preferred stock. On a pro forma basis and based upon the number of shares of Idera common stock and preferred stock issued in the acquisition, Idera equity holders immediately prior to the acquisition will own approximately 33% of the combined Company (on an as-converted, fully-diluted basis and excluding certain out-of-the-money options and warrants held by Idera’s equity holders) immediately after these transactions. The acquisition was unanimously approved by the Board of Directors of Idera and the Board of Directors of Aceragen. The closing of the transaction was not subject to the approval of Idera stockholders.

JMP Securities, a Citizens Company (JMP), is serving as exclusive strategic advisor to Idera and Morgan, Lewis & Bockius LLP is serving as legal counsel to Idera. Wedbush PacGrow is serving as exclusive strategic financial advisor to Aceragen, and Fenwick & West LLP and Hutchison PLLC are serving as legal counsel to Aceragen.

Following the acquisition, the Company has pro forma cash on hand of approximately \$27 million, which is expected to provide cash runway into 3Q 2023.

Additional details are available in an updated corporate presentation that can be found online at IderaPharma.com and www.Aceragen.com.

Conference Call and Webcast Details

Idera will host a conference call on September 28, 2022, at 5 p.m. ET to discuss the acquisition and provide more information about the Aceragen pipeline. To access the call, please dial 1-866-652-5200 (toll-free) or 1-412-317-6060 (international) and ask to join the Idera Pharmaceuticals call. To join the webcast, please visit <https://edge.media-server.com/mmc/p/quyahvdi>.

About Idera Pharmaceuticals

Idera is focused on the acquisition, development, and ultimate commercialization of drug candidates for rare disease indications characterized by small, well-defined patient populations with serious unmet needs. Following the acquisition, the combined company will operate as a biopharmaceutical company developing innovative therapeutics for rare and orphan pulmonary and rheumatic diseases with high unmet medical need.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included or incorporated in this press release, including, without limitation, statements regarding the Company's strategic alternatives, new development opportunities, financial position, funding for continued operations, cash reserves, projected costs, prospects, clinical trials, plans, expectations, strategies, projections and objectives of management, are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," "schedule," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are predictions based on the Company's current expectations and projections about future events and various assumptions. Idera cannot guarantee that it will achieve the plans, intentions, or expectations disclosed in its forward-looking statements and you should not place undue reliance on the Company's forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties, and other factors, which may be beyond Idera's control, and which may cause the actual results, performance, or achievements of the Company to differ materially from future results, performance, or achievements expressed or implied by such forward-looking statements. There are a number of important factors that could cause Idera's actual results to differ materially from those indicated or implied by its forward-looking statements including, without limitation: whether the Company will be able to successfully integrate the Aceragen operations; whether the Company's stockholders approve the conversion of the Series Z Preferred Stock; whether the Company's cash resources will be sufficient to fund the Company's continuing operations and the newly acquired Aceragen operations, including the liabilities of Aceragen incurred in connection with the completion of the transactions; whether the Company's products will advance into or through the clinical trial process when anticipated or at all or warrant submission for regulatory approval; whether such products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; whether, if the Company's products receive approval, they will be successfully distributed and marketed; whether the Company's collaborations will be successful; and whether the Company will be able to comply with the continued listing requirements of the Nasdaq Capital Market. All forward-looking statements included in this press release are made as of the date hereof and are expressly qualified in their entirety by this cautionary notice, including, without limitation, those risks and uncertainties described in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, and otherwise in the Company's filings and reports filed with Securities and Exchange Commission. While Idera may elect to do so at some point in the future, the Company does not assume any obligation to update any forward-looking statements and it disclaims any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise, except as may be required by law.

Important Additional Information and Where to Find It

Idera Pharmaceuticals, Inc., its directors and certain of its executive officers are deemed to be participants in the solicitation of proxies from Idera Pharmaceuticals' stockholders in connection with the matters to be considered at Idera Pharmaceuticals 2022 Special Meeting of Stockholders. Information regarding the names of Idera Pharmaceuticals' directors and executive officers and their respective interests in Idera Pharmaceuticals by security holdings or otherwise can be found in Idera Pharmaceuticals' proxy statement for its 2022 Annual Meeting of Stockholders, filed with the SEC on April 29, 2022. To the extent holdings of Idera Pharmaceuticals' securities have changed since the amounts set forth in Idera Pharmaceuticals' proxy statement for the 2022 Annual Meeting of Stockholders, such changes have been reflected on Initial Statements of Beneficial Ownership on Form 3 or Statements of Change in Ownership on Form 4 filed with the SEC. These documents are available free of charge at the SEC's website at www.sec.gov. Idera Pharmaceuticals intends to file a proxy statement and accompanying proxy card with the SEC in connection with the solicitation of proxies from Idera Pharmaceuticals stockholders in connection with the matters to be considered at Idera Pharmaceuticals' 2022 Special Meeting of Stockholders. Additional information regarding the identity of participants, and their direct or indirect interests, by security holdings or otherwise, will be set forth in Idera Pharmaceuticals' proxy statement for its 2022 Special Meeting, including the schedules and appendices thereto. **INVESTORS AND STOCKHOLDERS ARE STRONGLY ENCOURAGED TO READ ANY SUCH PROXY STATEMENT AND THE ACCOMPANYING PROXY CARD AND ANY AMENDMENTS AND SUPPLEMENTS THERETO AS WELL AS ANY OTHER DOCUMENTS FILED BY IDERA PHARMACEUTICALS WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE AS THEY WILL CONTAIN IMPORTANT INFORMATION.** Stockholders will be able to obtain copies of the proxy statement, any amendments or supplements to the proxy statement, the accompanying proxy card, and other documents filed by Idera Pharmaceuticals with the SEC for no charge at the SEC's website at www.sec.gov. Copies will also be available at no charge at the Investor Relations section of Idera Pharmaceuticals' corporate website at <https://ir.iderapharma.com/> or by contacting Idera Pharmaceuticals' Investor Relations at Idera Pharmaceuticals, Inc., 505 Eagleview Blvd., Suite 212 Exton, Pennsylvania 19341 or by calling Idera Pharmaceuticals' Investor Relations at (877) 888-6550.

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Idera Pharmaceuticals + Aceragen

A Business Combination to Create a Public Rare Disease Pulmonary & Rheumatology Company

September 2022



Important Information

The information provided in this presentation pertaining to the business combination (the "Business Combination") between Idera Pharmaceutical, Inc. ("Idera") and Aceragen, Inc. ("Aceragen") is for informational purposes only to assist interested parties in making their own evaluation and is not a solicitation of a proxy, consent or authorization related to or in respect of the Business Combination in any jurisdiction. Information contained in this presentation should not be relied upon as advice to buy or sell such securities. You should not construe the contents of this presentation as legal, tax, accounting or investment advice or a recommendation. You should consult your own counsel and tax and financial advisors as to legal and related matters concerning the matters described herein. No legally binding obligations will be created, implied, or inferred from this presentation or the information contained herein. The products outlined in this presentation are still under development. The features of the final product may be different, and nothing should be construed as a commitment by Idera.

Important Information

While the information in this presentation is believed to be accurate, Idera, Aceragen and their respective agents, advisors, directors, officers, employees and stockholders make no representation or warranties, expressed or implied, as to the accuracy, completeness or reliability of such information. Neither Idera, Aceragen, nor any of their respective affiliates, agents, advisors, directors, officers, employees and stockholders shall have any liability whatsoever, under contract, tort, trust or otherwise, to you or any person resulting from the use of the information in this presentation by you or any of your representatives or for omissions from the information in this presentation. We reserve the right to amend or replace the information contained herein, in part or entirely, at any time, and undertakes no obligation to provide you with access to the amended information or to notify you thereof.

The distribution of this presentation may also be restricted by law and persons into whose possession this presentation comes should inform themselves about and observe any such restrictions. The presentation is not directed to any person in any jurisdiction where (by reason of that person's nationality, residence or otherwise) the publication or availability of the presentation is prohibited. Persons in respect of whom such prohibitions apply must not access the presentation.

Forward-Looking Statements

Certain information in this presentation and oral statements made in any meeting are forward-looking and relate to the Company and its anticipated financial position, business strategy, events and courses of action. The use of words such as, but not limited to, "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," or "would" and similar words expressions are intended to identify forward-looking statements. Forward-looking statements are based on the opinions and estimates of management at the date the statements are made, and are subject to a variety of risks and uncertainties and other factors that could cause actual events or results to differ materially from those anticipated in the forward-looking statements. Although we believe that the expectations reflected in the forward-looking statements are reasonable, there can be no assurance that such expectations will prove to be correct. We cannot guarantee future results, level of activity, performance or achievements and there is no representation that the actual results achieved will be the same, in whole or in part, as those set out in the forward-looking statements.

By their nature, forward-looking statements involve numerous assumptions, known and unknown risks and uncertainties, both general and specific, that contribute to the possibility that the predictions, forecasts and other forward-looking information will not occur, which may cause the Company's actual performance and financial results in future periods to differ materially from any estimates of future performance, illustrations of performance results or results expressed or implied by such forward-looking statements. Important factors that could cause actual results to differ materially from

expectations include, but are not limited to: whether the Company will be able to succ operations and realize the anticipated benefits of the acquisition of Aceragen; whethe the clinical hold affecting the ACG-801 program; whether the Company's stockholder: Series Z Preferred Stock; whether the Company's cash resources will be sufficient to operations and the newly acquired Aceragen operations, including the liabilities of Ac with the completion of the Merger; whether the Company's products will advance into process when anticipated or at all or warrant submission for regulatory approval; whe approval from the U.S. Food and Drug Administration or equivalent foreign regulatory Company's products receive approval, they will be successfully distributed and marke collaborations will be successful; and whether the Company will be able to comply wil requirements of the Nasdaq Capital Market. New risks and uncertainties may emerge possible to predict all risks and uncertainties. All forward-looking statements included of the date hereof and are expressly qualified in their entirety by this cautionary notice those risks and uncertainties described in the Company's Annual Report on Form 10- 31, 2021, and otherwise in the Company's filings and reports filed with the Securities ("SEC"). Readers are cautioned that this list of factors should not be construed as ext

The forward-looking statements contained in this presentation are expressly qualified Except as required by law, we undertake no obligation to update or revise publicly an whether as a result of new information, future events or otherwise, after the date on w to reflect the occurrence of unanticipated events. Readers are cautioned not to place looking statements.

Important Additional Information and Where to Find It

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Late-Stage Rare Disease Pipeline

- Three advanced rare disease programs, with approvals expected to begin as early as 2H 2024
- Expected strong product exclusivity and 2 priority review vouchers
- Significant potential for near-term news flow with clinical development and regulatory updates across portfolio

Strong Revenue Potential

- Combined annual peak sales for current three clinical programs estimated to exceed \$650M
- Significant revenue anticipated to begin in 2025 from potential national stockpiling with nominal sales expense
- Additional indication opportunities

Financial Strength

- Cash and planned concurrent financing expected to provide runway into 3Q 2023
- Non-dilutive DoD funding of up to \$40m available
- Access to public markets

Exec Lead

- Vin Milano become C Board; 4 a Board mer continue
- John Tayl CEO, to le rare diseas
- Leadership to repres both Idera

Management Team



John Taylor[†]
Chief Executive Officer

Serial entrepreneur with significant experience developing therapeutics for orphan and rare diseases.

Responsible for +\$900 million in executed transactions and investments over 25-year career.

CEO/co-founder of Aceragen.



Dan Salain[†]
Chief Operating Officer

30 years pharma leadership experience including product development, manufacturing, QA/QC, distribution, business development, and corporate operations.

Developed and launched over 30 products globally.

COO/co-founder of Aceragen.



John Kirby*
Chief Financial Officer

More than 25 years of public-company finance and business experience from his roles with small to large-sized public pharma companies, including ViroPharma and AstraZeneca, and in public accounting with KPMG.

Responsible for raising over \$175 million.



Carl Kraus[†]
Chief Medical Officer

Infectious disease physician with 20+ years of clinical experience treating patients and 15 years CMO experience in related drug development.

Former medical officer in the Office of Antimicrobial Products at FDA;

CEO/founder of Arrevus.



Bryant Lim*
Chief Business Officer & General Counsel

25+ years legal and business experience across multiple small & large commercial- and development-stage public pharma companies.

Former Chief Compliance Officer of Incyte Corp. and CBO/GC Idera.

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**Current Idera Management Team member*

†Former Aceragen Management Team member

Late-Stage Orphan Pulmonary & Rheumatology Company



Expected to have 3 advanced studies underway in less than 6 months:

| | | Pre-clinical | Phase 1 | Phase 2 | Phase 3 |
|--|---|--------------|--------------------|---------|---------|
| ACG-701 <i>(sodium fusidate)</i> | Melioidosis | | Enrolling now | | |
| | Cystic fibrosis <i>(acute exacerbations)</i> | | Initiation Q4 2022 | | |
| ACG-801 <i>(acid ceramidase)</i> | Farber disease | | Initiation Q1 2023 | | |

Aceragen has established a late-stage pipeline

- 8 clinical and regulatory milestones anticipated by the end of 2024 expected to drive increasing value
- NDA/BLA submissions for approval expected beginning in 2024/2025
- Current 3 indications expected to exceed \$650m in aggregate annual sales at peak

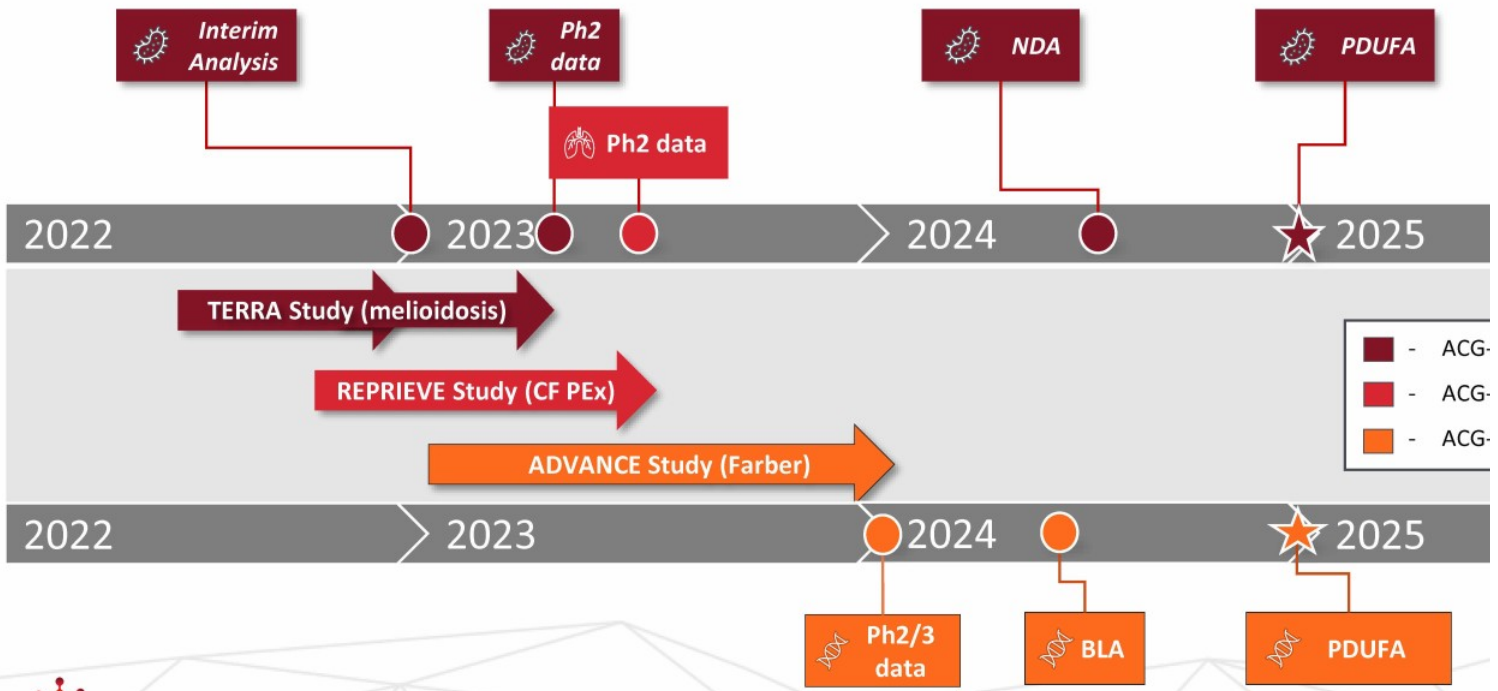
Pipeline has future potential in other indications

- Potential to apply existing products to complementary, unserved/underserved indications



Multiple Near-Term Milestones Expected

Including potential NDA/BLA submissions for approvals in 2024/2025



ACG-701

Patented Formulation of Sodium Fusidate

Initial Target Indications

Cystic fibrosis pulmonary exacerbations (PEX) – *Commercial i*
Meliodosis - *Strategic national stockpile (melio SNS) indicati*

Future Indications

Undisclosed future indications planned with additional capita

Mechanism / Function

Mucin inhibitory
Anti-inflammatory
Anti-infective

Product History

Generic version approved ex-US; significant history in treatm
methicillin-resistant Staphylococcus aureus (“MRSA”) and rel
that cause exacerbations in the lungs

Administration

Proprietary oral dosage (BID; loading dose)

Regulatory Status / Designations

Orphan¹, Fast Track¹, QIDP¹ and Tropical Disease/MCM (PRV-

Expected Approval

2024 (melio SNS) / 2026 (CF)

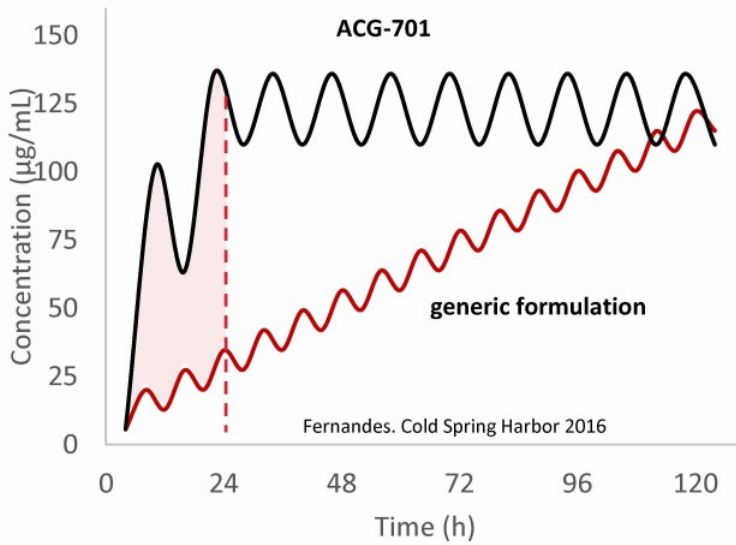
Peak Annual Sales Estimate (CF & melio SNS)

\$500m+



ACG-701 Provides Superior PK over the ex-US Generic Formulation

...and is a unique, patented formulation of sodium fusidate

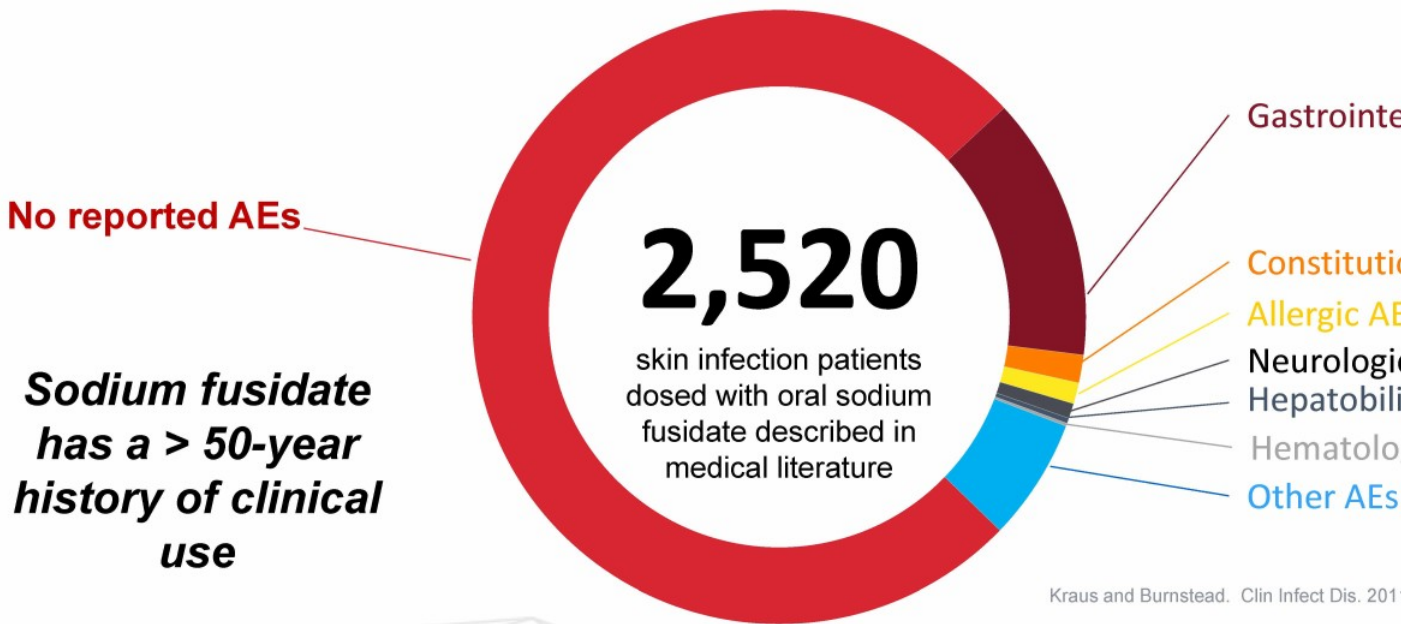


- ACG-701 steady state is achieved **4 days earlier** than the generic formulation
- ACG-701 has a far higher C_{max} for *S. aureus* (**>3X**) than the generic formulation

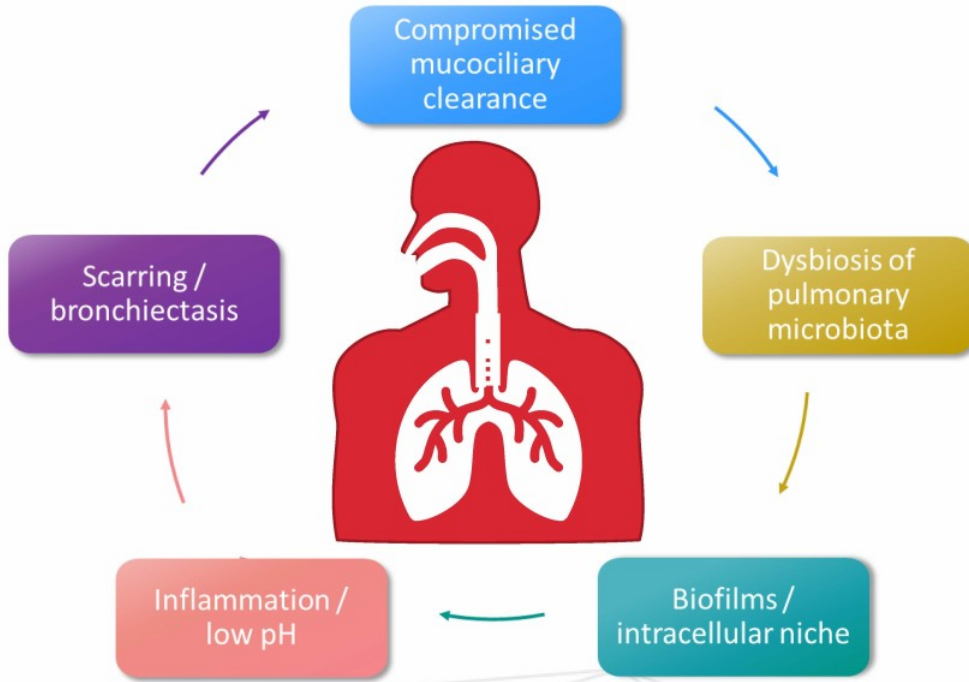
ACG-701 has potential for 12 years of exclusivity from first approval in the US (NCE/Orphan Status) and potential for 10 years of exclusivity in Japan and EU (Orphan Status)

Sodium Fusidate Has a Strong Safety Profile in the Published Literature

ACG-701 Trials Have Demonstrated Similar Safety



ACG-701 is Well-Suited to Directly Address the Vicious Cycle of Respiratory Disease



ACG-701 PROPERT

DECREASES MUCIN PRO

POWERFUL ANTI-IN

BIOFILM PENETRA

ACCUMULATES INTRAC

HIGH POTENCY AT L

ANTI-INFLAMMAT

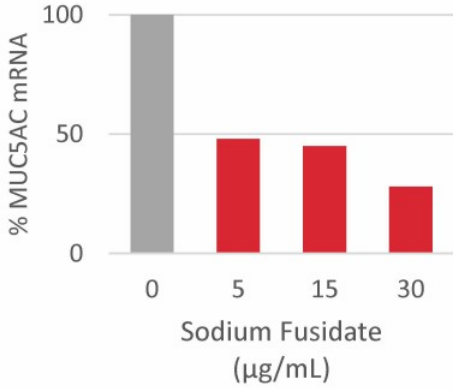


Sodium Fusidate's Properties Suggest it Could Be Efficacious for Treating Progressive Pulmonary Diseases



Decreases mucin expression

MUC5AC is a prevalent mucin during PEx and can increase by >900% compared to baseline



Source: study # UNC-102-0611, unpublished

Sodium fusidate inhibits MUC5AC expression in a dose-dependent manner

Relevant antimicrobial properties

S. aureus is common in progressive lung diseases; > 25% are antibiotic resistant (MRSA)

MICs Against MRSA

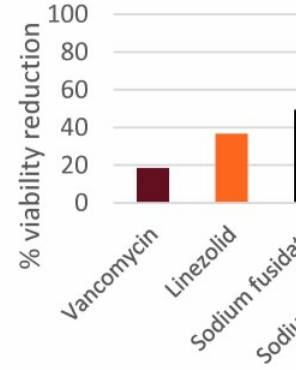
| Drug | MIC ₉₀ (µg/mL) |
|-----------------|---------------------------|
| Sodium fusidate | 0.25 |
| Trimethoprim | 0.5 |
| Vancomycin | 1 |
| Teicoplanin | 1 |
| Daptomycin | 1 |
| Linezolid | 2 |
| Rifampin | >16 |
| Clindamycin | >256 |

Source: McGee et al., AAC 2011

Sodium fusidate is the most potent oral anti-MRSA agent available outside the US

Biofilm penetration

Biofilm-related infection is one of the most progressive pulmonary diseases



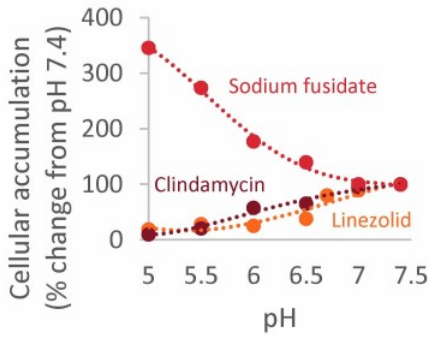
Sodium fusidate is active against MRSA and its activity is synergistic with other antibiotics



Sodium Fusidate's Properties Suggest it Could Be Effective for Treating Progressive Pulmonary Disease (cont.)

Accumulates intracellularly

Intracellular pathogens impacting pulmonary disease are more challenging to target due to poor antibiotic intracellular accumulation

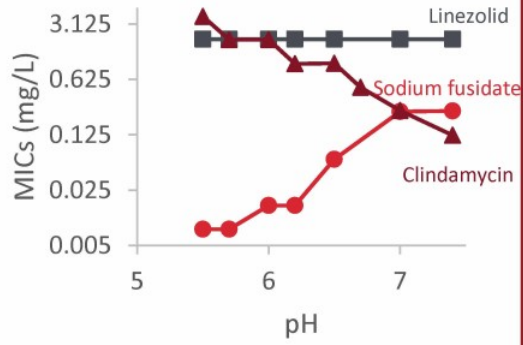


Source: Lemaire et. al. CID 2011

Sodium fusidate accumulates intracellularly; this phenomena increases as pH declines

Effective at low pH

Diseased lungs result in declining pH, potentially decreasing the potency of most antibiotics

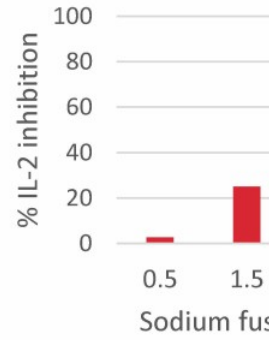


Source: Lemaire et. al. CID 2011

Sodium fusidate's activity increases >30-fold as pH declines from pH 7.5 to 5.5

Anti-inflammatory

Pro-inflammatory cytokines (including IL-2, TNF- α , and IFN γ) worse



Sodium fusidate inhibits pro-inflammatory cytokines (including IL-2, TNF- α , and IFN γ)

CF Pulmonary Exacerbations (CF PEx)

Principal Driver of Declining Lung function

- Exacerbations and related complications account for nearly two-thirds of CF patient deaths
- Despite treatment advances, current rates are still approximately 1-2x/year
- No therapies currently approved to treat CF PEx
- Polypharmacy approach typically used to address increased mucin production, inflammation and bacteria that often “hide” intracellularly

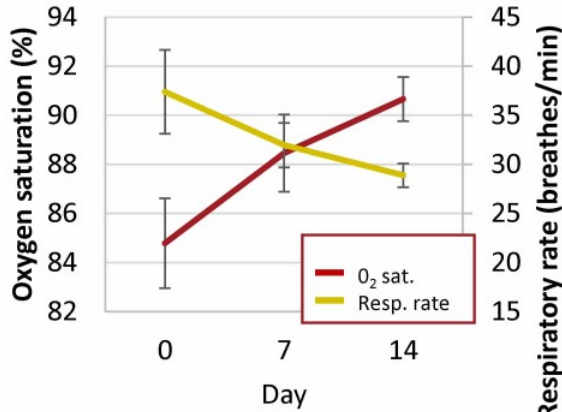


Image source:
<https://emedicine.medscape.com/article/2000000/overview>; updated Sept. 28, 2020

Sodium Fusidate in CF PEx Trial

SODIUM FUSIDATE HAS PREVIOUSLY BEEN EVALUATED IN CYSTIC FIBROSIS PEx

Efficacy of Sodium Fusidate in CF PEx

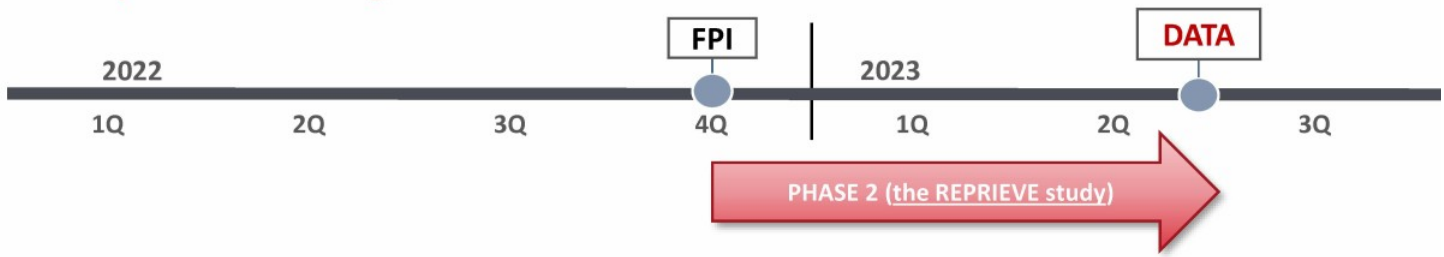


Kraemer et al. 1982

- Prior clinical trial with standard of care in C PEx resulted in **improvement in lung function**
 - **Improvement in oxygen saturation**
 - **Improvement of respiratory rate**
- **Sodium fusidate is recommended for treatment of CF exacerbations** by UK and AU treatment guidelines (focused on antimicrobial activity)
- Potential for anti-inflammatory, anti-infective and mucin inhibition in **one oral drug**

The REPRIEVE Study in CF PEx

Expected to begin in 4Q 2022



THE REPRIEVE STUDY DESIGN

- Randomized, double-blind, placebo-controlled study evaluating ACG-701 treatment for newly diagnosed pulmonary exacerbations in CF patients
- Two-week oral BID treatment plus two-week follow-up
- Clinical benefit in pulmonary exacerbations can include multiple outcome measures; REPRIEVE will capture multiple clinical events inclusive of CRISS, FEV1, and antimicrobial regimen changes through Day 14 in a single statistical measure
- DTRA program covers most development expenses aside from clinical trial

80
Adult CF pts

22 s

US DoD Funding Facilitates Commercial Opportunity for ACG-701

CF

Treatment of Pulmonary Exacerbations

Largely De-risked:

Financial – CF Foundation funding

Compound – Included in UK/AU treatment guidelines

Safety – +50-year history of clinical use with a good safety profile

Anticipated approval: **2025**

Melioidosis

Tropical Disease/Medical Countermeasure

Financial – Secured DTRA funding for program to approval

Mechanism – Enhanced potency at low pH

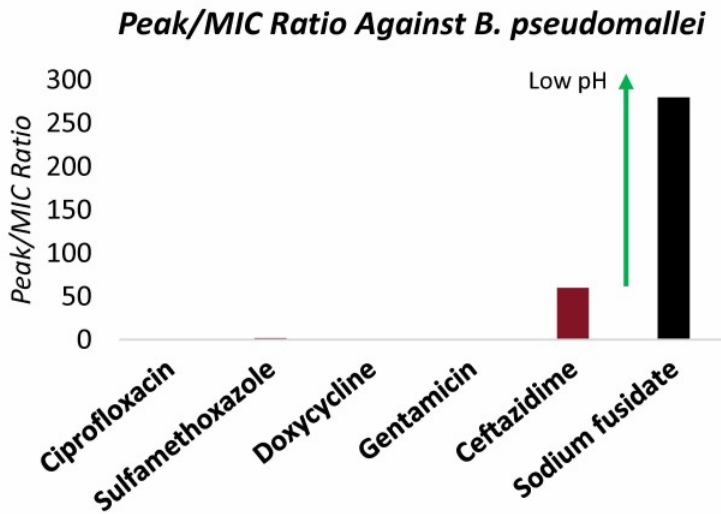
Anticipated approval: **2024**

- Clinical investigation of treatment approved will meet a remaining patients
- Differentiated product profile & reimbursement for severe org
- Melioidosis indication is a medical countermeasure and tropical review voucher (PRV) candidate
- Defense Threat Reduction Agency partnership is funding all the development and a significant 701 NDA requirements; CF development limited to trial and sNDA costs

Peak annual sales potential melioidosis + CF exc

ACG-701's Potency Against *B. pseudomallei* Shows Potential in Treating Melioidosis

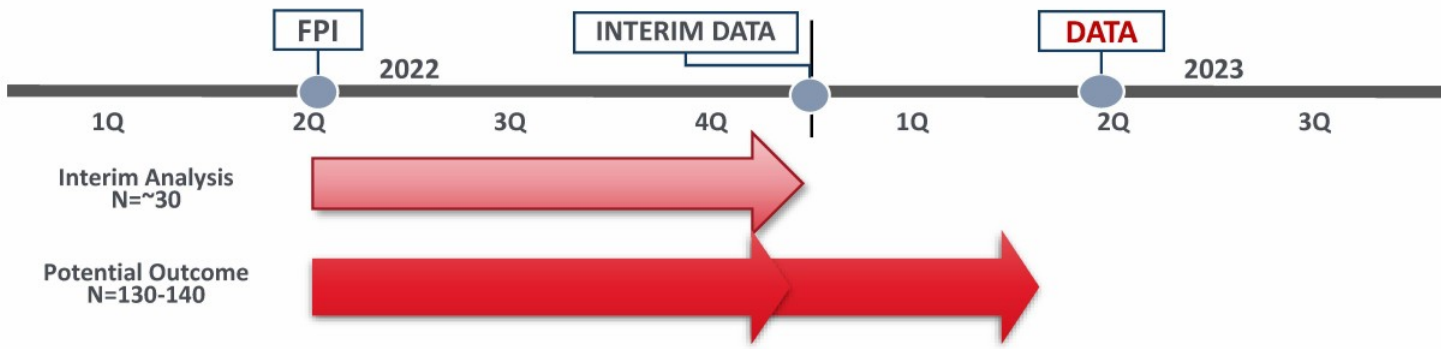
\$51M in DTRA funding awarded toward clinical and regulatory develop



- Sodium fusidate has demonstrated clinical potency against *B. pseudomallei* which aligns favorably with potential efficacy
- Sodium fusidate's properties (e.g., intracellular accumulation, efficacy at low pH, etc.) potentially a promising candidate to treat melioidosis
- ACG-701 achieves steady state within 24 hours of eradication of the microbe before it has a chance of developing resistance
- Due to virulence, intrinsic resistance, aerosol transmission, melioidosis is designated as a top 1 bioterrorist by the US DoD
- No FDA approved therapies

Source: Pooled from Still et al. CID 2011; Meinig et al. ASM Poster #2340, 2022; Mosovsky et al. AAC, 2014 and FDA product labels

The TERRA Study of ACG-701 in Melioidosis is Underway



THE TERRA PHASE 2 STUDY

- Randomized, double-blind, placebo-controlled study in hospitalized melioidosis patients; two-week BID dosing with two-week follow-up
- Melioidosis has a non-homogenous clinical presentation; TERRA will capture multiple clinical events inclusive of mortality, organ failure, sepsis and treatment modifications through Day 14 in a single statistical measure.
- Interim analysis included to allow power re-estimation for sample expansion
- Study could be expanded into a Ph 3 study



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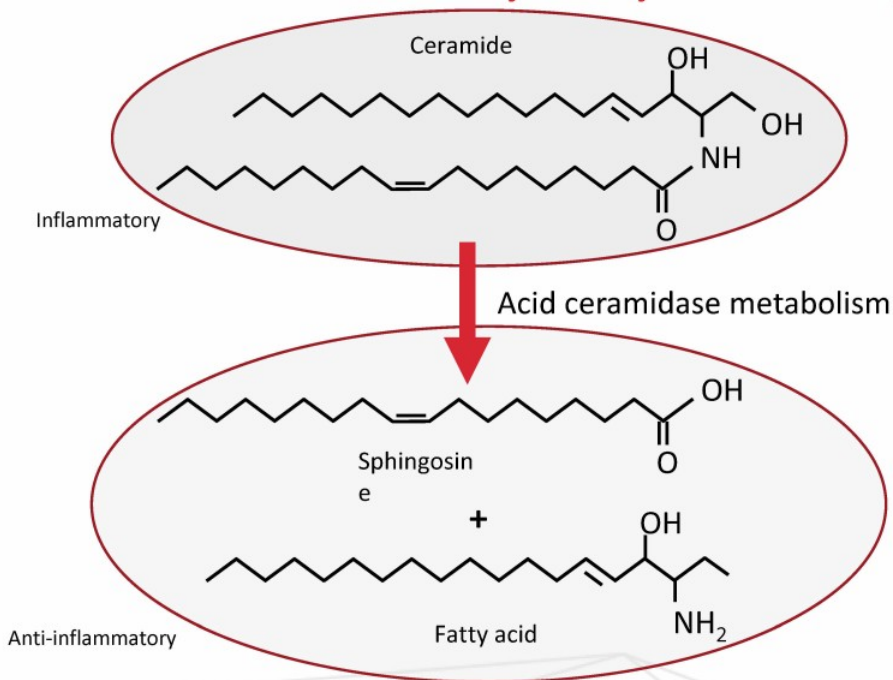
ACG-801

Acid Ceramidase

| | |
|---|--|
| Initial Target Indication | Farber disease (<i>genetic loss of function</i>) |
| Potential Future Indications | Spinal muscular atrophy with progressive myoclonic epilepsy <i>loss of function</i> Reducing frequency of cystic fibrosis PEx (<i>epigenetic loss of fu lungs</i>) |
| Mechanism / Function | Ceramide metabolism to resolve accumulation |
| Administration | Bi-weekly infusions |
| Regulatory Status / Designations | Orphan, Fast Track, and Rare Pediatric Disease (PRV) |
| Expected Approval | 2024 |
| Annual Peak Sales Estimate | \$150m |

ACG-801 (Recombinant Human Acid Ceramidase; rhAC)

An anti-inflammatory catalyst with multiple potential applications



- Acid ceramidase breaks down (toxic inflammation) into sphingosine (strong anti-inflammatory) and fatty acids
- Ceramide is implicated in multiple inflammatory disease states including Farber disease, cystic fibrosis dermatitis, and ulcerative colitis
- Treatment with acid ceramidase proven to be effective in multiple models of inflammatory disease

Farber Disease

A progressive monogenic lysosomal storage disorder (LSD)

- Mutations in the acid ceramidase gene lead to toxic levels of ceramide accumulation
- Patients with the most severe phenotype die by age two, most commonly of respiratory failure
- Worldwide prevalence is expected to be similar to MPS VI (1000+ patients)

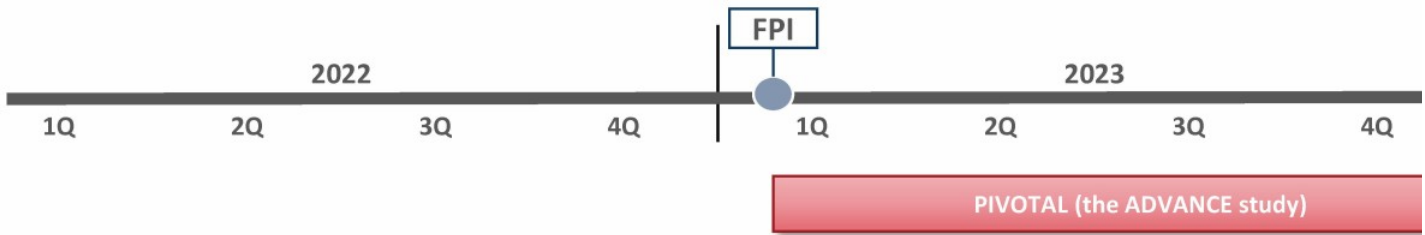


Jarisch et al. Eur J Pediat

**\$150M in worldwide annual peak sales
estimated for ACG-801 treatment of Farber**

ACG-801 for Farber Disease

Aceragen is planning a single, harmonized trial for US/EU submission



THE ADVANCE STUDY DESIGN

- Randomized, double-blind, placebo-controlled, first-in-human, all-comer Farber study; IV Q2W treatment
- Clinical benefit in Farber may be evaluable short term or long term. Can include multiple outcome measures. ADVANCE will objectively measure nodule changes and capture patient-specific disease burden improvement (e.g., pain, mobility, impact score) through week 28

15

Farber Ped
& Adult Pts

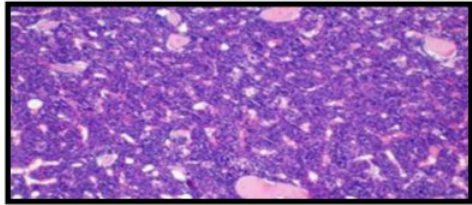
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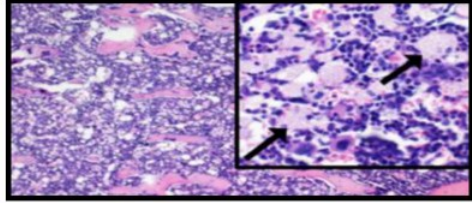
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ACG-801 for Farber Disease: Pre-Clinical Data

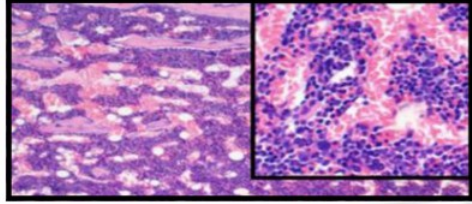
ACG-801 SHOWN TO BE EFFECTIVE IN FARBER MOUSE MODEL



WT mouse
(bone marrow)



Farber mouse
untreated
(black arrows:
macrophage infiltrates)



Farber mouse
+ ACG-801
(resolution of
macrophage infiltrates)

ACG-801 treatment of Farber mice results

- ↓ Reduction of ceramide deposits in target tissues
- ↓ Reduction of inflammatory biomarkers/cytokines to wild type levels
- ↓ Amelioration of bone, joint, and soft tissue lesions (pathophysiology same as clinical endpoint)
- ↑ Additional 3-week lifespan in newborn mice

Source: ACG-801 Investigator's Brochure

Enzyme Replacement Therapy (ERT) Animal Model Success Expected to Be Highly Predictive of Hu Efficacy and Dose

| Therapy (Disease) | Pre-Clinical Effective Dose | Approved Dose | | Disease Model Key |
|-------------------------|---|---------------------|------|---|
| Aldurazyme (MPS I) | 0.5-2mg/kg once weekly (canine) | QW | 0.58 | Lysosomal target & substrate reduction |
| Fabrazyme (Fabry) | 0.3-3mg/kg twice monthly (rodent) | QOW | 1 | |
| Naglazyme (MPS VI) | 1-2mg/kg once weekly (feline) | QW | 1 | |
| Myozyme (Pompe) | 10-100mg/kg twice monthly (rodent) | QOW | 20 | |
| Kanuma (LALD) | 0.35-3mg/kg twice monthly (rodent) | QOW | 1 | |
| ACG-801 (Farber) | 1-10mg/kg once weekly or twice monthly (rodent) | Under Investigation | | Reduction of substrate infiltration Endpoints may translate |

ACG-801 animal data anticipated to predict clinical benefit, demonstrate opportunity to reverse disease

Summary: Key Goals Through 2024

Potential regulatory submissions for approval to follow based on data

CF PEx:

- ❖ Complete Ph2 2Q 2023

Melioidosis:

- ❖ Complete Ph2 2Q 2023

Farber Disease

- Complete Ph2 Q1 2024

❖ Projected cash available is expected to provide the Company with capital runway into Q3 2023

