



Cingulate Inc.

Initiating Coverage with BUY and \$7.00 Target

Large market opportunities for its PTR platform and 2 drugs to treat ADHD. We believe expected positive milestones and clinical data over the next year to be strong catalysts for stock.

Initiating with BUY: We are initiating coverage of Cingulate with a BUY rating and a 12-month price target of \$7.00. Cingulate is a clinical stage biopharmaceutical company developing drugs utilizing its PTR drug delivery platform technology that enables once-daily tablets of multi-dose therapies.

Focused on ADHD: The company's initial focus is on the treatment of Attention Deficit/Hyperactivity Disorder (ADHD). The company is developing two proprietary first-line stimulant medications, CTx-1301 and CTx-1302, for the treatment of ADHD for all patient segments. The company also has a third product to treat anxiety, CTx-2103, in a formulation (preclinical trials) stage.

Precision Timed Release (PTR): The underlying medicines in CTx-1301 (dexmethylphenidate) and CTx-1302 (dextroamphetamine) are well established approved drugs for ADHD, but the differentiation in Cingulate's new drugs is their usage of its Precision Timed Release (PTR) drug delivery platform. CTx-1301 and CTx-1302 utilize a flexible core tableting technology designed to allow for the release of drug substance at specific, pre-defined time intervals, unlocking the potential for once-daily, multi-dose tablets.

CTx-1301: The company is preparing to start Phase 3 clinical trials for CTx-1301 in Q4 2022. If the study results are positive, Cingulate plans to submit the NDA (new drug application) for CTx-1301 in late 2023.

CTx-1302: The company plans to initiate a Phase 1/2 bioavailability study for CTx-1302 in ADHD patients in 2023. If the results from this study are successful, the company plans to initiate a pivotal Phase 3 clinical trials in all patient segments for CTx-1302 in 2024 with top-line results expected in 2025.

Large market potential: ADHD is a chronic neurobehavioral and developmental disorder that affects millions of children, adolescents and adults. In the United States, approximately 6.4 million, or 11%, of children and adolescents aged 4-17 have been diagnosed with ADHD. Adult ADHD prevalence in the United States is estimated at approximately 11 million patients, or 4.4%, of the population. Total ADHD medication sales in the United States have grown approximately 8% each year since 2010 with sales of all ADHD medications reaching approximately \$18.3 billion in 2020.

Clinical data can be catalyst: Cingulate anticipates starting/finishing its various clinical trials over the next year. We believe achieving key milestones and strong positive data will likely be catalysts for the stock.

However, challenges exist: Cingulate operates in a highly competitive environment and competes against a wide range of other drugs, therapeutics, and treatments. There is the chance that competing therapeutic treatments for ADHD or its PTR technology may be developed and launched before the company's drugs are launched.

Positive high risks versus high rewards: Overall, concerns outweighed by growth prospects and valuation. Cingulate's 2 main drugs still have long development roads left and the high risks of clinical trials failures, but we believe the ~billion dollars market potential presents high rewards for the risks.

Current valuation attractive: We calculate a 12-month price target for shares of Cingulate to be \$7.00 based on a NPV analysis, representing significant upside from the current share price. We believe this valuation appropriately balances out the company's high risks with the company's high growth prospects and large upside opportunities.

Company Description

Cingulate, based in Kansas City, KS, is a clinical stage biopharmaceutical company developing drugs utilizing its PTR drug delivery platform technology that enables once-daily tablets of multi-dose therapies.

October 3, 2022

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Stock Data

Exchange:	NasdagCM
52-week Range:	0.94 - 5.15
Shares Outstanding (million):	11
Market cap (\$million):	\$12
EV (\$million):	\$4
Debt (\$million):	\$0
Cash (\$million):	\$8
Avg. Daily Trading Vol. (\$million):	\$0.2
Float (million shares):	9
Short Interest (million shares):	~0.1
Dividend, annual (yield):	\$0 (NA%)

Revenues (US\$ million)

	<u>2021A</u> <u>(Cur.)</u>	<u>2022E</u> (Cur.)	<u>2023E</u> (Cur.)	
Q1 Mar	0A	0A	OE	
Q2 Jun	0A	0A	OE	
Q3 Sep	0A	0E	OE	
Q4 Dec	<u>0A</u>	<u>0E</u>	<u>0E</u>	
Total	0A	0E	0E	
EV/Revs	N/A	N/A	N/A	

Earnings per Share (pro forma)

	<u>2021A</u> (Cur.)	<u>2022E</u> (Cur.)	<u>2023E</u> (Cur.)
Q1 Mar		(0.44)A	(0.46)E
Q2 Jun		(0.36)A	(0.45)E
Q3 Sep		(0.38)E	(0.46)E
Q4 Dec		<u>(0.45)E</u>	<u>(0.46)E</u>
Total	(2.79)A	(1.63)E	(1.83)E
P/E	N/A	N/A	N/A

Important Disclosures

Ascendiant Capital Markets LLC seeks to do business with companies covered by its research team. Consequently, investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making an investment decision.

For analyst certification and other important disclosures, refer to the Disclosure Section, located at the end of this report, beginning on page 31.

COVERAGE INITIATION

Rating: BUY

Ticker:	CING	
Price:	\$1.07	
Target:	\$7.00	





Exhibit 1: Cingulate Inc. Stock Price (1-Year since IPO in December 2021)

Source: https://bigcharts.marketwatch.com/

INVESTMENT THESIS

We are initiating coverage of Cingulate with a BUY rating and a 12-month price target of \$7.00.

Cingulate, based in Kansas City, KS, is a clinical stage biopharmaceutical company developing drugs utilizing its PTR drug delivery platform technology that enables once-daily tablets of multi-dose therapies. The company's initial focus is on the treatment of Attention Deficit/Hyperactivity Disorder (ADHD). The company is developing two proprietary first-line stimulant medications, CTx-1301 and CTx-1302, for the treatment of ADHD for all patient segments: children, adolescents, and adults. In addition, the company has a third product to treat anxiety, CTx-2103, in a formulation (preclinical trials) stage.

The company's proprietary Precision Timed Release (PTR) drug delivery platform technology is aimed to build and advance a pipeline of next-generation pharmaceutical products designed to improve the lives of patients suffering from frequently diagnosed conditions characterized by burdensome daily dosing regimens and suboptimal treatment outcomes. Its PTR platform incorporates a proprietary Erosion Barrier Layer (EBL) designed to allow for the release of drug substance at specific, pre-defined time intervals, unlocking the potential for once-daily, multi-dose tablets.

The company is preparing to start Phase 3 clinical trials for CTx-1301 in Q4 2022. If the study results are positive, Cingulate plans to submit the NDA (new drug application) for CTx-1301 in late 2023. The company plans to initiate a Phase 1/2 bioavailability study in ADHD patients for CTx-1302 in 2023. If the study results are positive, the company plans to initiate a pivotal Phase 3 clinical trials for CTx-1302 in 2024 with results expected in 2025.



Exhibit 2: Cingulate Inc. Corporate Overview





About Cingulate®

Cingulate is a clinical stage biopharmaceutical company focused on the development of innovative new product candidates for the treatments of Attention Deficit/Hyperactivity Disorder (ADHD) and anxiety associated disorders.

Developing Next-Generation Medications in Billion-Dollar Markets

Precision Timed Release™ (PTR™) Platform Unlocks the Possibility for 'True' Once-daily, Multi-dose Tablets





Source: Company reports.

CTx-1301's main active pharmaceutical ingredient is dexmethylphenidate, which is a widely used and approved drug (sold under the brand name of Focalin among others as it is available as a generic). Dexmethylphenidate is a strong central nervous system (CNS) stimulant medication used to treat attention deficit hyperactivity disorder (ADHD) in those over the age of five years.

CTx-1302's main active pharmaceutical ingredient is dextroamphetamine, which is a widely used and approved drug (sold under the brand name of Dexedrine among others as it is available as a generic). Dextroamphetamine is a central nervous system (CNS) stimulant and an amphetamine that is prescribed for the treatment of attention deficit hyperactivity disorder (ADHD).



The underlying medicines in CTx-1301 (dexmethylphenidate) and CTx-1302 (dextroamphetamine) are well established approved drugs for ADHD, but the differentiation in Cingulate's new drugs is their usage of its Precision Timed Release (PTR) drug delivery platform. CTx-1301 and CTx-1302 utilize a flexible core tableting technology with target product profile designed to deliver a rapid onset and last the entire active day with a controlled descent of drug level and favorable tolerability.

Cingulate believes there is still a significant, unmet need within the current treatment paradigm for a true once-daily ADHD stimulant medications with lasting duration and a superior side effect profile to better serve the needs of patients throughout their entire active-day.

Exhibit 3: Cingulate's Precision Timed Release (PTR) Platform

Vast Pipeline of Next-Generation Medications Beyond ADHD

 \checkmark Leverage PTR platform faster and with less cost in other therapeutics areas

- ✓ Market Criteria:
 - \$1Bn+ in peak sales
 - Next-generation mediations with significant improvement over existing therapies



Source: Company reports.

Attention-Deficit / Hyperactivity Disorder (ADHD) is one of the most common neurodevelopmental disorders of childhood. It is usually first diagnosed in childhood and often lasts into adulthood. People with ADHD may have trouble paying attention, controlling impulsive behaviors (may act without thinking about what the result will be), or be overly active.

ADHD is a chronic neurobehavioral and developmental disorder that affects millions of children, adolescents and adults. In the United States, approximately 6.4 million, or 11%, of children and adolescents aged 4-17 have been diagnosed with ADHD. Among this group, 80% receive treatment and 65% demonstrate clinical ADHD symptoms that persist into adulthood. Adult ADHD prevalence in the



United States is estimated at approximately 11 million patients, or 4.4%, of the population, almost double the size of the child and adolescent segment combined. Currently, approximately 20% of the adult ADHD population receives treatment, however an increasing number of adult patients are being diagnosed and seeking treatment causing the adult ADHD market to grow approximately 10% year over year. Total ADHD medication sales in the United States have grown approximately 8% each year since 2010 with sales of all ADHD medications reaching approximately \$18.3 billion in 2020.





The Cingulate Solution for ADHD Patients & Providers





Cingulate had its IPO in December 2021 (Q4 2021), so it has had two full quarters as a publicly traded company. Because the company is a clinical stage drug development company, it currently generates no revenue and incurs significant losses as it funds its drug development.

The company does not provide specific quarterly financial guidance, but we believe that R&D expenses should increase as the company expands clinical trial activities. Going forward, we believe operating expenses of ~\$4 million is a reasonable near term quarterly burn rate. The company expects continued progress on its drug development milestones in 2022/23. We do not expect the company to experience revenue until its drugs make significant progress towards FDA approval (either from product sales or from the sales of drug marketing rights to new partners), which is likely at least several years away.

For 2022, we expect a net loss of \$19 million and EPS of \$(1.63). For 2023, we expect a net loss of \$22 million and EPS of \$(1.83). The company estimates that the additional clinical and filing costs to advance CTx-1301 to a NDA filing (in late 2023) will be ~\$16.5 million. The company will also require additional funding for its other 2 drugs in development (CTx-1302 and CTx-2103).

We believe investors should be focused on its progress on its drug development, which will likely take at least several years before a potential FDA approval. Within the next year, the company plans to launch 2 Phase 3 and 1 Phase 1/2 trials and we should get Top-Line data from these studies.

The company's balance sheet has \$8 million in cash and no debt as of June 2022. This does not include the recent \$5 million in debt (3 years at 15%) that it raised in August from a Board member (Peter Werth). In December 2021, the company had its IPO (initial public offering) selling 4.2 million shares at \$6.00 per share (raising ~\$25 million). We believe the company has enough cash through 2022, but we believe it will need to raise new capital in early 2023. The company has guided to having enough cash through Q1 2023.

Our investment thesis factors in an uncertain drug development process and very competitive industry which is offset by the very large potential upside opportunities created from a successful drug. We believe that the current valuation for Cingulate has already factored in many of its risks (principally drug approval and successful commercialization) but is under valuing its overall growth prospects and product portfolio, resulting in a positive risk versus reward scenario for an investment in Cingulate.

We believe the current valuation is attractive.

Based on our expectations and assumptions and our NPV analysis, we calculate a 12-month price target for shares of Cingulate to be \$7.00, representing significant upside from current share price. We believe this valuation appropriately balances out the company's high risks with the company's high growth prospects and large upside opportunities. We acknowledge that Cingulate is still at an early stage in its drug development and product commercialization, but we believe key milestones over the next year should be positive catalysts for the stock.

INVESTMENT RISKS

Long and Uncertain Drug Development Cycles

Cingulate is highly dependent upon securing drug approvals for its products in order to sell them (produce revenue). The drug development cycle can be long (average of 12 years), expensive (average of \$350 million), complicated, and uncertain. On average only about 10% of drugs entering clinical trials ever make it to final approval. Because Cingulate's main 2 drugs (CTx-1301 and CTx-1302 which are both to treat ADHD) are still early in development in various Phase 1/2/3 trials, there are still significant risks and a long time horizon to receive FDA approval. One benefit that Cingulate has is that the underlying medicines in CTx-1301 (dexmethylphenidate) and CTx-1302 (dextroamphetamine) are well established approved drugs for ADHD, with the potential approvals for Cingulate based on its Precision Timed Release (PTR) drug delivery platform. We estimate that it likely will be at least three years before either drugs can receive FDA approval. With a high likelihood of binary outcomes (either success or failure), the risks are high but the potential rewards can also be very high as well.



Product Commercialization Risks

Even after obtaining drug approvals, there is still a chance that commercial success will not be achieved (due to competition, changes in the market, lack of reasonable reimbursements, or lack of market acceptance). While there are currently many therapeutics to treat ADHD, Cingulate aims to develop a much better drug for ADHD treatment. There is the chance that other potential therapeutic treatments and options may be developed and launched before the company's drugs are launched. In addition, Cingulate will need to replace existing therapies and treatments being used currently as standards of care (especially since the underlying medicines for CTx-1301 and CTx-1302 are already being used). Like most health care drugs, the company will also need to get suitable insurance and government reimbursements for its products.

High Level of Competition

Cingulate operates in a highly competitive environment and competes against a wide range of other biopharmaceutical companies that are attempting to replicate or already have comparable treatments for ADHD as the company's drugs. Some of these competitors are much larger or have greater resources, and proprietary technology; which could result in lower projected sales for its drugs and higher costs, reduced margins, and lowered profitability for the company. Even if Cingulate were to be successful with its drug development, its products will have to compete with existing or new standards of care.

Concentrated Product Pipeline

The company is currently developing 2 main drug therapeutics (CTx-1301 and CTx-1302), and is very early with a 3rd CTx-2103 for anxiety. If Cingulate were to experience difficulties with development of any of these, then it may have a material negative impact on its business and financials as there are no meaningful products which can offset.

Coronavirus and Economic Uncertainties

While healthcare costs tends to be less correlated with economic activity and income levels due to their nondiscretionary nature, major deterioration in economic conditions tends to result in an overall decline in consumer spending. This was demonstrated during the 2008 and 2009 Great Recession and global economic slowdown. While consumer spending levels and economic conditions have rebounded since and have been strong the past several years, the global macroeconomic environment can change significantly quickly as was shown with the start of the COVID-19 pandemic in March 2020. Since then, due to huge government stimulus the U.S. economy is now very strong (though there has been some recent slowdowns in 2022). However, the pandemic has still negatively impacted many businesses and has been a huge disruption to the U.S. (and global) economy. This includes biotechs as many have seen FDA drug development reviews, feedback, and approvals delayed along with disruptions in clinical trials. Further economic weakness may result in depressed enterprise and consumer spending levels; this may have a negative impact on Cingulate, its business partners, government, and consumers.

Capital Markets Risks

We believe Cingulate has enough cash to fund its operations through 2022, but we estimate that it will need to raise capital by Q1 2023. We believe that it will be at least several years before the company can be cash flow self-sufficient from operations. Many biopharmaceutical companies fund their operations from the sale of equity or debt capital until their products reach commercial success or until they sell off the commercial rights to other companies. Biopharmaceuticals ("biotechs") valuations tend to fluctuate widely, and they have been very weak in 2022 (mainly due to a weak general stock market and larger weakness and volatility for small/microcap stocks), there is always the chance that market interests and valuations for companies in this industry to further decline significantly. The lack of a long shares trading history along with share price volatility since its recent IPO (with a stock price range of 0.94 - 5.15 since its IPO (though we note most of the extreme price decline volatility was concentrated in the immediate period post IPO)) in Cingulate's share price may make capital raising much more difficult and expensive.



VALUATION

We are initiating coverage of Cingulate with a BUY rating and a 12-month price target of \$7.00, which is based on a NPV analysis. As the company is a clinical stage drug development company, it currently generates no revenue and significant losses so traditional valuation metrics are not useful. We believe a more accurate valuation should take into consideration the potential value of its product pipeline. We do acknowledge that this valuation is complex and requires a large number of forward assumptions that we have to estimate that may be imprecise and may vary significantly from actual results. This is particularly so for a company like Cingulate which is still in early clinical trials with its 3 main drugs.

However, we believe our assumptions are fair and provide a reasonable basis for our valuation analysis. Our analysis considers future estimated revenue from each of its major product pipelines (based on estimated future sales, a probability rate of success, and discounted this back to a current value), currently focused on its CTx-1301 and CTx-1302 drugs for ADHD and its CTx-2103 drug for anxiety. We apply a high discount rate and a low probability of success to capture the high uncertainties associated generally with drugs in development. We then added up the values, made an assumption about future investments required and allocated the value based on current share count. Based on our NPV analysis, we arrived at our 12-month price target of \$7.00, which we believe appropriately balances out the company's risks with its high growth prospects.

Cingulate recently (in December 2021) had its IPO (initial public offering) so there is not a lot of share price trading history for the company yet. In December 2021, the company had its IPO selling 4.2 million shares of stock at \$6.00 per share (raising ~\$25 million). Though the share price since has been weak (~-80%) to \$1.07 currently (and has traded between \$0.94 and \$5.15 in the past year and \$0.94 and \$2.00 in the past 6 months), we believe this is more likely due to limited news flow typical for clinical stage drug development companies along with general stock price weakness and volatility with small/microcap biotech stocks. We believe that there are near term catalysts that can drive the stock (particularly for key milestones expected in 2022/23). As the company is likely to make significant progress (and milestones) in its drug development and product commercialization over the next several years, we believe this will result in much improved visibility into future cash flows and higher share price. Although it is very likely that the company will have to keep raising capital to achieve its product development goals, we believe that positive progress will make future financings accretive to current shareholders.



Exhibit 5: Cingulate Inc. Stock Price (6-Months)

Source: https://bigcharts.marketwatch.com/



We believe the company has a steady balance sheet with enough cash through 2022, but that it will need to raise capital in early 2023 to fund clinical trials and to achieve its strategic goals.

We expect valuations for Cingulate to improve as visibility into cash flow generation becomes clearer (though we acknowledge that product commercialization is likely at least 3 years away), resulting in significant upside to the current share price. We also want to note that investors' interest in drugs development to treat and prevent ADHD are high with many companies in this area (including those with existing and approved drugs in the market) due to the large market opportunities given lack of good treatment options and the high incidence rate.

Exhibit 6: Company Valuation (DCF) (in millions)

Valuation of Products (in millions)

Product	Estimat	ied NPV	% of Success	Calculated NPV	Discount Rate	Estimated	Annual Sales	% of Market Share	Market Potentia	l per year
CTx-1301 (ADHD)	\$	125	25%	\$ 500	25%	\$	125	25%	\$	500
CTx-1302 (ADHD)	\$	11	15%	\$ 75	50%	\$	38	25%	\$	150
CTx-2103 (Anxiety)	\$	4	10%	\$ 40	50%	\$	20	20%	\$	100
Total	\$	140								
Estimated additional investments (& debt) required	\$	60								
Current Value for existing shareholders	\$	80								
Shares Outstanding (mils)		11								
Estimated Value per share	\$	7.00								

Source: Ascendiant Capital Markets estimates

COMPANY

Cingulate, based in Kansas City, KS, is a clinical stage biopharmaceutical company developing drugs utilizing its PTR drug delivery platform technology that enables once-daily tablets of multi-dose therapies. The company's initial focus is on the treatment of Attention Deficit/Hyperactivity Disorder (ADHD). The company is developing two proprietary first-line stimulant medications, CTx-1301 and CTx-1302, for the treatment of ADHD for all patient segments: children, adolescents, and adults. In addition, the company has a third product to treat anxiety, CTx-2103, in a formulation (preclinical trials) stage.

The company's proprietary Precision Timed Release (PTR) drug delivery platform technology is aimed to build and advance a pipeline of next-generation pharmaceutical products designed to improve the lives of patients suffering from frequently diagnosed conditions characterized by burdensome daily dosing regimens and suboptimal treatment outcomes. Its PTR platform incorporates a proprietary Erosion Barrier Layer (EBL) designed to allow for the release of drug substance at specific, pre-defined time intervals, unlocking the potential for once-daily, multi-dose tablets.

The company is preparing to start Phase 3 clinical trials for CTx-1301 in Q4 2022. If the study results are positive, Cingulate plans to submit the NDA (new drug application) for CTx-1301 in late 2023. The company plans to initiate a Phase 1/2 bioavailability study in ADHD patients for CTx-1302 in 2023. If the study results are positive, the company plans to initiate a pivotal Phase 3 clinical trials for CTx-1302 in 2024 with results expected in 2025.



Cingulate Therapeutics LLC was formed in November 2012 as a Delaware limited liability company. In May 2021, Cingulate Inc. was formed to serve as a holding company in anticipation of the company becoming a publicly traded company. In December 2021, the company had its IPO (initial public offering) selling 4.2 million shares at \$6.00 per share (raising ~\$25 million). Prior to the IPO, Cingulate's equity owners were referred to as "Members" who owned Members' capital (equity capital of the company). Members' capital were all converted to equity shares as part of the IPO process. As of December 2021, the company had 16 employees.

Exhibit 7: Cingulate Management Team

Name	Age	Position
Executive Officers:		
Shane J. Schaffer, PharmD	47	Chief Executive Officer and Chairman of the Board
Louis G. Van Horn, MBA	63	Executive Vice President and Chief Financial Officer
Laurie A. Myers, PhD	65	Executive Vice President and Chief Operating Officer
Craig S. Gilgallon, Esq.	50	Executive Vice President, General Counsel and Secretary
Raul R. Silva, MD	64	Executive Vice President and Chief Science Officer
Matthew Brams, MD	58	Executive Vice President and Chief Medical Officer



Shane J. Schaffer

Raul R. Silva

Louis G. Van Horn

Shane J. Schaffer, PharmD is a Co-Founder of Cingulate Therapeutics and has served as the Chairman and CEO since its inception. Dr. Schaffer is a 25-year pharmaceutical industry veteran with experience in pharmaceutical drug development, commercialization and biotech commercial operations. During his career, he has held positions at Pfizer, Novartis and Sanofi (including predecessor companies).

Raul R. Silva, MD is a Co-Founder of Cingulate Therapeutics and serves as CSO. He is a practicing child and adolescent psychiatrist who has served as Associate Professor and Vice Chairman of Child and Adolescent Psychiatry at New York University School of Medicine in New York City. Prior to that, he was the Executive Director of Rockland Children's Psychiatric Center. He also served as the Deputy Director in the Division of Child and Adolescent Psychiatry at Bellevue Hospital Center, also in New York City.

Louis G. Van Horn serves as CFO. Mr. Van Horn is a strategic finance leader whose business acumen is based over 35 years of experience as a strategic finance leader serving in executive leadership roles with a variety of industries including pharmaceuticals as well as Big 4 CPA experience.



PRODUCT

Cingulate's key technology is its proprietary Precision Timed Release (PTR) drug delivery platform technology that enables once-daily tablets of multi-dose therapies. The PTR drug delivery platform technology aims to build and advance a pipeline of next-generation pharmaceutical products designed to improve the lives of patients suffering from frequently diagnosed conditions characterized by burdensome daily dosing regimens and suboptimal treatment outcomes. This PTR platform incorporates a proprietary Erosion Barrier Layer (EBL) designed to allow for the release of drug substance at specific, pre-defined time intervals, unlocking the potential for once-daily, multi-dose tablets.

Exhibit 8: Cingulate Pipeline

Pipeline Cingulate currently has two (2) product candidates, CTX-1301 and CTX-1302, that are being developed to serve the approximate \$18 billion annual U.S. ADHD market. A third product candidate, CTX-2103, is being developed to serve the roughly \$5 billion U.S. anxiety market.

Source: Company reports.

The company's initial focus for its PTR technology is for the treatment of Attention Deficit/Hyperactivity Disorder (ADHD). The company is developing two proprietary first-line stimulant medications, CTx-1301 and CTx-1302, for the treatment of ADHD for all patient segments: children, adolescents, and adults. In addition, the company has a third product to treat anxiety, CTx-2103, in a formulation (preclinical trials) stage.

CTx-1301's main active pharmaceutical ingredient is dexmethylphenidate, which is a widely used and approved drug (sold under the brand name of Focalin among others as it is available as a generic). Dexmethylphenidate is a strong central nervous system (CNS) stimulant medication used to treat attention deficit hyperactivity disorder (ADHD) in those over the age of five years.

CTx-1302's main active pharmaceutical ingredient is dextroamphetamine, which is a widely used and approved drug (sold under the brand name of Dexedrine among others as it is available as a generic). Dextroamphetamine is a central nervous system (CNS) stimulant and an amphetamine enantiomer that is prescribed for the treatment of attention deficit hyperactivity disorder (ADHD) and narcolepsy.

The underlying medicines in CTx-1301 (dexmethylphenidate) and CTx-1302 (dextroamphetamine) are well established approved drugs for ADHD, but the differentiation in Cingulate's new drugs is their usage of its Precision Timed Release (PTR) drug delivery platform. CTx-1301 and CTx-1302 utilize a flexible core tableting technology with target product profile designed to deliver a rapid onset and last the entire active day with a controlled descent of drug level and favorable tolerability.



Cingulate believes there is still a significant, unmet need within the current treatment for a true once-daily ADHD stimulant medications with lasting duration and a superior side effect profile to better serve the needs of patients throughout their entire active-day.

CTx-1301 is Cingulate's lead investigational drug for the treatment of ADHD. The company aims to get FDA approval under Section 505(b)(2), which is usually much faster and cheaper than the typical route of Section 505(b)(1) which is used for novel drugs (with limited clinical data) as 505(b)(2) uses data from prior public studies and sources. 505(b)(2) approval pathways are typically used for drugs that are very comparable and similar (active pharmaceutical ingredient (API)) to drugs already FDA approved and there is a history of drug safety and efficacy.

Cingulate is currently preparing a CTx-1301 Phase 3 (called Mastery), fixed-dose, pediatric and adolescent safety and efficacy study, and anticipate dosing the first patient in Q4 2022. Results from this study are expected in the second half of 2023. In order to meet the pharmacology requirement for the CTx-1301 New Drug Application (NDA) submission, the company plans to complete a food effect study in Q4 2022. In addition, Cingulate plans to initiate an adult dose-optimization study (Phase 3b) to assess the onset and duration of efficacy in the second half of 2023. This Phase 3b trial is supplementary and is not required for the CTx-1301 NDA submission. The company had completed a proof-of-concept trial in human subjects in October 2020 and announced positive results from this Phase 1/2 study. Assuming the company receives positive clinical results from its Phase 3 trial and food effect study, Cingulate plans to submit the NDA (new drug application) for CTx-1301 in late 2023 under the Section 505(b)(2) pathway.

CTx-1302 is Cingulate's second investigational drug for the treatment of ADHD. The company plans to initiate a Phase 1/2 bioavailability study (called Accomplish) in ADHD patients in 2023. If the results from this study are successful, the company plans to initiate a pivotal Phase 3 clinical trials in all patient segments for CTx-1302 in 2024 with top-line results expected in 2025.

CTx-2103 (buspirone) is Cingulate's third investigational drug, with this drug's target is for the treatment of anxiety. CTx-2103 is a form of buspirone, which is a widely used and approved drug (sold under the brand name of Buspar among others as it is available as a generic). Buspirone is a medication primarily used to treat anxiety disorders.

CTx-2103 is still very early in development as it is in a formulation (preclinical trials) stage. Just recently, in September, the company announced positive results from its formulation study for CTx-2103 (which was completed in June). In the study, the pharmacokinetics were evaluated for three multi-layered, timed-release oral tablets and one immediate release dose of buspirone. Based on the dissolution profile seen in the data, the CTx-2103 30 mg tablet achieved the solubility required to deliver a triple release of buspirone hydrochloride. Based on this data, CTx-2103 appears to provide patients with entire-day efficacy, safety, and convenience in a once-daily anxiety medication.







Source: Company reports.

Attention-Deficit / Hyperactivity Disorder (ADHD) is one of the most common neurodevelopmental disorders of childhood. It is usually first diagnosed in childhood and often lasts into adulthood. People with ADHD may have trouble paying attention, controlling impulsive behaviors (may act without thinking about what the result will be), or be overly active.

ADHD is a chronic neurobehavioral and developmental disorder that affects millions of children, adolescents and adults. In the United States, approximately 6.4 million, or 11%, of children and adolescents aged 4-17 have been diagnosed with ADHD. Among this group, 80% receive treatment and 65% demonstrate clinical ADHD symptoms that persist into adulthood. Adult ADHD prevalence in the United States is estimated at approximately 11 million patients, or 4.4%, of the population, almost double the size of the child and adolescent segment combined. Currently, approximately 20% of the adult ADHD population receives treatment, however an increasing number of adult patients are being diagnosed and seeking treatment causing the adult ADHD market to grow approximately 10% year over year. Total ADHD medication sales in the United States have grown approximately 8% each year since 2010 with sales of all ADHD medications reaching approximately \$18.3 billion in 2020.

ADHD is marked by an on-going pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning and/or development. According to the American Academy of Child and Adolescent Psychiatry, common manifestations of ADHD in children and adolescents include:

Hyperactivity: Children always seem to be in motion. A child who is hyperactive may move around touching or playing with whatever is around, or talk continually. During story time or school lessons, the child might squirm around, fidget, or get up and move around the room. A teenager or adult who is hyperactive may feel restless and need to stay busy all the time.



- Impulsivity: Children often blurt out comments without thinking first. They may often display their emotions without restraint. They may also fail to consider the consequences of their actions. Such children may find it hard to wait in line or take turns. Impulsive teenagers and adults tend to make choices that have a small immediate payoff rather than working toward larger delayed rewards.
- *Inattentiveness:* Inattentive children may quickly get bored with an activity if it's not something they really enjoy. Organizing and completing a task or learning something new is difficult for them. As students, they often forget to write down a school assignment or bring a book home. At any age, an inattentive person may often be easily distracted, make careless mistakes, forget things, have trouble following instructions, or skip from one activity to another without finishing anything.

Exhibit 11: ADHD (Attention-Deficit / Hyperactivity Disorder) Growing Problem

The number of US children ever diagnosed with ADHD has changed over time



Estimated number of U.S. children ages 3-17 years who ever had a diagnosis of ADHD,¹ in millions

Percent of children with ADHD who had at least one other disorder³





Adult ADHD patients typically suffer from restlessness, impulsivity, difficulty with time management, trouble regulating emotions and difficulty managing finances. Adults with ADHD report experiencing an internal sense of fidgetiness and restlessness and experience greater difficulty communicating with others. Upon entering the job market, many adults have difficulty gaining employment and are at increased risk of termination due to repeated tardiness or absenteeism. Adults with ADHD earn approximately 30% less and are 10% less likely to be employed versus their unaffected peers. Additionally, adults with ADHD are more likely to exhibit a variety of comorbidities including drug and alcohol abuse, social anxiety and depression.

ADHD in both children and adults has a negative impact not only on the individual but on their families, friends and peers and because of its prevalence as one of the most commonly diagnosed behavioral disorders, a critical impact on society, the healthcare system and the economy at large.



Source: Company reports.

Stimulants are the most commonly prescribed class of medications for ADHD, accounting for more than 90% of all ADHD medication prescriptions. Stimulants are Schedule II controlled substances, classified by the U.S. DEA (Drug Enforcement Administration) as drugs with a high potential for abuse and have stricter regulations than lower class drugs. Stimulants are believed to work by enhancing the effects of dopamine and norepinephrine neurotransmitters in the brain. Approximately 70 million stimulant prescriptions were written in 2020. In contrast, non-stimulant medications are typically deployed as second line or adjunctive therapies and account for 9-10% of all ADHD medication prescriptions. Currently, the ADHD market is dominated by four main stimulant medications: Vyvanse[®], Adderall[®] XR, Concerta[®], and Focalin[®] XR. These products were approved and became available between 2000 and 2007 and were believed to revolutionize the ADHD treatment paradigm by finally providing a solution to avoid the late morning second dose of



stimulant medication then required by ADHD patients. These four medications today account for nearly \$12 billion or 75% of the spending in the stimulant category and 54% of all stimulant prescriptions.

Exhibit 13: Leading ADHD Drugs

ADHD Market Currently Dominated by 4 Stimulant Products

Major Unmet Medical Needs Persist							
ADHD BRANDS	APPROVED	ATTR	IBUTES ¹		UNMET	NEEDS ¹	
		Onset	Duration (less onset)	Fast Onset of Action ≤ 30 min	Entire Active- Day Efficacy*	Minimize Crash/Rebound	Avoid Booster ²
Vyvanse®	2007	2 hours	12 hours	×	×	Data Not Available	×
Adderall® XR	2001	1 ½ hours	10 ½ hours	×	×	Data Not Available	×
Concerta®	2000	2 hours	10 hours	×	×	Data Not Available	×
Focalin® XR	2005	30 mins	11½ hours	\checkmark	×	Data Not Available	×

* Entire-active day efficacy defined as less than or equal to a 30 min onset of action with 14-16 hours of duration vs. placebo

ADHD Market Leaders Do Not Provide "Built-In Booster"

Market Leaders Stop Delivery of Medication 4-5 Hours After Administration

ADHD BRANDS	ATTR	IBUTES ¹			
	Onset	Duration (less onset)	DOSE 1 / STYLE / TIME	DOSE 2 / STYLE / TIME	DOSE 3 / STYLE /TIME
Vyvanse®	2 hours	12 hours	100% PRODRUG SUSTAINED RELEASE OVER 2 – 3 HOURS	0	0
Adderall® XR (and generics)	1 ½ hours	10 ½ hours	50% IMMEDIATE RELEASE	50% IMMEDIATE RELEASE AT HOUR 4	0
Concerta® (and generics)	2 hours	10 hours	22% IMMEDIATE RELEASE	78% SUSTAINED RELEASE OVER 4-5 HOURS	0
Focalin® XR (and generics)	30 mins	11½ hours	50% IMMEDIATE RELEASE	50% IMMEDIATE RELEASE AT HOUR 4	0

¹ Information based upon product Package Inserts, and Summary Basis of Approvals

60% use short-acting 'booster' dose <u>every day!</u>



Extended-release, or long-acting, dosage forms of stimulant medications are most frequently deployed as the first-line treatment for ADHD and constitute approximately 60% of ADHD stimulant prescriptions by volume and nearly 85% of the dollars. Most of these extended-release dosage forms are approved for once-daily dosing in the morning and were designed to eliminate the need for redosing during the day. However, with the current 'once-daily' extended-release dosage forms, most patients still receive a second or "booster" dose for administration later in the day (typically in the early afternoon) to achieve entire active-day coverage and suffer from a multitude of unwanted side effects as a result.

Unfortunately, as designed, all four of the mostly commonly prescribed stimulant drugs deliver all the drug substance during the morning hours. As a result, most patients still require additional medication to cover the remainder of their active day. Currently, 60% of ADHD patients require an afternoon 'booster/recovery' dose due to lack of duration, slow onset of efficacy, and the crash or rebound effects in the early afternoon. Additionally, their PK-PD release profiles are such that they leave patients significantly impaired by crash and rebound effects even while on therapy.

Patients and practitioners report, that an ideal ADHD stimulant medication would provide all of the following characteristics: entire active-day duration (14-16 hours); immediate onset of action (within 30 minutes); ability to minimize or avoid crash / rebound effects associated with rapid decline in medication blood levels; and elimination of the need for short-acting stimulant booster/recovery doses.

Thus, Cingulate believes there is a significant, unmet need within the current treatment paradigm for true once-daily ADHD stimulant medications with lasting duration and a superior side effect profile to better serve the needs of patients throughout their entire active-day. Cingulate is targeting the ADHD stimulant-based treatment market, with an estimated U.S. market size of \$15.3 billion in 2020.

The company's two proprietary, first-line stimulant medications: CTx-1301 (dexmethylphenidate) and CTx-1302 (dextroamphetamine), are being developed for the treatment of ADHD, in the three main patient segments: children (ages 6 -12), adolescents (ages 13-17), and adults (ages18+). Both CTx-1301 and CTx-1302 are designed to address the key shortcomings of currently approved stimulant therapies by: providing an immediate onset of action (within 30 minutes); offering 'entire active-day' duration; eliminating the need for a 'booster/recovery' dose of short-acting stimulant medications; minimizing or eliminating the rebound/crash symptoms associated with early medication 'wear-off;' and providing favorable tolerability with a controlled descent of drug blood levels.

Furthermore, by eliminating the 'booster' dose used by up to 60% of ADHD patients in conjunction with their primary medication, the company believes its drug candidates will provide important societal and economic benefits: reducing the abuse and diversion associated with short-acting stimulant medications; allowing physicians to prescribe one medication versus two; allowing patients to pay for one medication versus two; and allowing payers to reimburse one medication versus two.



Exhibit 14: Cingulate Precision Timed Release (PTR) Technology





Computed Tomography Scan (CT scan) of CTx-1301 tablet

Source: Company reports.

The company is developing ADHD medications capable of achieving true once-daily dosing using its PTR drug delivery platform technology. Its CTx-1301 and CTx-1302 drug candidates both contain three releases of active pharmaceutical ingredient (API) combined into one small tablet dosage form (smaller than many comparable single dose ADHD products). Each release of API is separated with a proprietary Erosion Barrier Layer (EBL), a functional excipient that is designed to gradually erode throughout the day to provide controlled drug release at specific time intervals, allowing for a target efficacious period of up to 16 hours.

CTx-1301 is mainly dexmethylphenidate which is already widely used for the treatment of ADHD in 6 years and older. CTx-1301 is a trimodal extended-release tablet, based on tablet-in-tablet technology, that provides three releases of dexmethylphenidate at precise times, ratio, and modality of release.

CTx-1301 release profile is as follows:

- Release #1: An initial immediate-release, or IR, dose providing 35% of the total daily dose beginning within five to six minutes after administration and designed to achieve therapeutic efficacy within 30 minutes; and
- Release #2: Three hours after the administration of the dosage form, the first delayed, sustained release (DR1) provides 45% of the total daily dose released over 90 minutes; and
- Release #3: Seven hours after the administration of the dosage form, a second delayed, immediate release (DR2, the builtin-booster) provides 20% of the total daily dose released over approximately 30 minutes.

CTx-1302 is mainly dextroamphetamine which is already widely used for the treatment of ADHD in 6 years and older. CTx-1302 is a trimodal extended-release tablet, based on tablet-in-tablet technology, that provides three releases of dextroamphetamine at precise times, ratio, and modality of release.

CTx-1302 release profile is as follows:

- Release #1: An initial immediate-release, or IR, dose providing 45% of the total daily dose begins within five to six minutes after administration is designed to achieve therapeutic efficacy within 30 minutes; and
- Release #2: Three hours after the administration of the dosage from, the DR1 provides 35% of the total daily dose released over 90 minutes; and



• Release #3: Seven hours after the administration of the dosage form, a DR2, the built-in-booster provides 20% of the total daily dose released over approximately 30 minutes.

The company's innovative Precision Timed Release (PTR) drug delivery platform technology incorporates a proprietary Erosion Barrier Layer (EBL). This EBL provides control of drug release at precise, pre-defined times with no release of drug prior to the intended release. The technology is an erodible barrier layer that is wrapped around a drug containing core to give a tablet-in-tablet dose form. The barrier layer is designed to erode at a controlled rate until eventually the drug is released from the core tablet.





Exhibit 16: Cingulate's ADHD Drugs Differentiation

CTx-1301 (d-MPH) and CTx-1302 (d-AMP)

Ideal Design Provides Exclusive Ability to Overcome Unmet Needs

Onset Duration 30 mins Up to 16 hours 30 mins Up to 16 hours 30 mins Up to 16 hours	DOSE 1 / STYLE / TIME 35% IMMEDIATE RELEASE 45% IMMEDIATE RELEASE Fast Acting (≤ 30 min)	45% SUSTAINE MINUTE 35% SUSTAINE MINUTE	Y STYLE / TIME D RELEASE OVER 90 S AT HOUR 3 D RELEASE OVER 90 S AT HOUR 3 T NEEDS Avoid	DOSE 3 / STYLE /TIME 20% IMMEDIATE RELEASE AT HOUR 7 20% IMMEDIATE RELEASE AT HOUR 7
30 mins hours 30 mins Up to 16 hours ARGET ATTRIBUTES Onset Duration mins Up to 16 hours	45% IMMEDIATE RELEASE Fast Acting (≤ 30 min) √	MINUTE 35% SUSTAINE MINUTE UNMET	IS AT HOUR 3 D RELEASE OVER 90 IS AT HOUR 3	RELEASE AT HOUR 7 20% IMMEDIATE
ARGET ATTRIBUTES Onset Duration mins Up to 16 hours	Fest Acting (≤ 30 min)	MINUTE UNMET	IS AT HOUR 3	
Onset Duration mins Up to 16 hours	(≤ 30 min)	Entire Active-		
mins Up to 16 hours	(≤ 30 min)		Avoid	
1			Crash/Rebound	Avoid Boos te r
	\checkmark	\checkmark	\checkmark	\checkmark
roduct available es all unmet need		lowing poter	affords our pro ntial advantage	es over current
ntire active-day' of of action need for covery dose	✓ Signi ✓ Lowe	ice abuse / d ficantly impr er costs to pa	oved tolerabili atients, provide	ninating boost ty ers, and payers
iee	d for very dose	✓ Signi very dose nd rebound effect ✓ Abili	 ✓ Significantly imprive ✓ d for ✓ Lower costs to particular ✓ Ability to optimiz 	 ✓ Significantly improved tolerability ✓ d for ✓ Lower costs to patients, provide



Exhibit 17: CTx-1301 Phase 2 Study Results



At the Individual Level, Tri-modal Delivery is Clear

Entire Active-Day Efficacy, Stop the Crash & Rebound, Eliminate the Booster Dose







Cingulate believes that its PTR platform has the potential to provide patients and physicians with differentiated pharmaceutical treatment options that will enhance patient compliance and improve health outcomes in several additional therapeutic areas. The company plans to leverage its PTR platform technology to expand and augment its drug pipeline by identifying and developing additional assets in other therapeutic areas where one or more or more active pharmaceutical ingredients (API) need to be delivered several times a day at specific, pre-defined time intervals and released in a manner that would offer significant improvement over existing therapies.

Cingulate's long term goal is to be a leading, innovative biopharmaceutical company focused on the development, manufacturing and commercialization of next generation pharmaceutical products that utilize its PTR drug delivery platform technology to create dosing schedules and drug release profiles that will improve the lives of patients suffering from a multitude of frequently diagnosed conditions.

Key initial elements of its business strategy are to:

- Complete development and obtain regulatory approval for CTx-1301 for the treatment of ADHD.
- Advance development of CTx-1302 for the treatment of ADHD.
- Successfully commercialize CTx-1301 and CTx-1302.
- Advance clinical trials for CTx-2103 for the treatment of anxiety.
- Maximize the potential of its PTR platform to develop additional product candidates in new indications.
- Acquire or in-license additional assets or programs complement its portfolio or leverage its technology.
- Further strengthen its intellectual property portfolio.
- Capitalize on its existing cGMP Manufacturing Expertise.



Exhibit 19: Commercialization Strategy

Commercialization to Drive Revenue

Changing dynamics in ADHD commercial landscape

- Ability to dominate share of voice
 - Concerta, Adderall XR, Focalin XR are all 0 off-patent with no promotion
 - Vyvanse loss of exclusivity ~August 2023 0
- New entrants lack major promotional efforts, field forces, and revenue

Maximize Access for Patients and Providers

- Clinical, Practical, and Societal Story:
 - Efficacy and Tolerability
 - One versus Two Prescriptions
 - Abuse & Diversion
 - Rebates & Net to Plan Cost
 - PBM's driven by rebate guarantees to payers; estimated >\$2B last year*
 - ADHD is a high brand utilization market with high-cost generics at 55-90% of branded drug cost*

Cingulate's Comprehensive Commercial Model

- Branded product of choice ~ Patients, Providers, & Payers \geq
- Strategic partnership to maximize market access, distribution, promotion across all channels ≻
 - Psychiatry / Neurology & Pediatrics / Family Practice encompass 84% of ADHD market*
 - Maximize and retain NPV to Cingulate

Source: Company reports.

Exhibit 20: Intellectual Properties

Exclusivity: IP, Agreements, and Trade Secrets

Intellectual property rights expected to provide exclusivity through 2035 at a minimum

- OralogiK™ Erosion Barrier Layer
 - Five (5) patents granted (US & Global) expiry dates ranging from 2031 to 2035,
 - One (1) OralogiK™ patent pending (US, Europe)
- Three (3) Cingulate product specific patents under prosecution with USPTO and global entities
 - Pharmacokinetics
- Pharmacodynamics
- Formulation, Precise Timing, Ratio of API
- Trimodal release of API
- •

Exclusivity agreements

- Compression technology exclusivity for branded Cingulate products
- Significant modifications and exclusive process technologies incorporated

Trade Secrets

Methods, tools, processes, designs, and equipment trade secrets





FINANCIALS

Cingulate's fiscal year ends on December 31. We expect its next earnings report (for Q3 2022 ending September) to be in mid-November. Cingulate had its IPO in December 2021 (Q4 2021), so it has had two full quarters as a publicly traded company. Because the company is a clinical stage drug development company, it currently generates no revenue and incurs significant losses as it funds its drug development.

Exhibit 21: Cingulate Historical and Projected Financials

FYE Dec 31					
(in millions except EPS)	2019A	2020A	2021A	2022E	2023E
Total Revenue	0	0	0	0	0
Operating income (loss)	(11.6)	(7.1)	(20.7)	(18.4)	(20.8)
Net income	(11.5)	(7.2)	(20.7)	(18.5)	(21.6)
EPS			\$ (2.79)	\$ (1.63)	\$ (1.83)

Source: Company reports and Ascendiant Capital Markets estimates.

Recent Results (fiscal Q2 ending June 2022)

Cingulate's recent financial performance is reflective of its developmental stage. In its Q2 2022 report (on August 11, 2022), the company reported no revenue and net loss was \$4.0 million. Operating expenses were \$4.0 million, mainly due to drug development costs and general and administrative expenses. Q2 EPS was \$(0.36).

The company does not provide specific quarterly financial guidance, but we believe that R&D expenses should increase as the company expands clinical trial activities. Going forward, we believe operating expenses of ~\$4 million is a reasonable near term quarterly burn rate. The company expects continued progress on its drug development milestones in 2022/23. We do not expect the company to experience revenue until its drugs make significant progress towards FDA approval (either from product sales or from the sales of drug marketing rights to new partners), which is likely at least several years away. We have modeled relatively steady operating costs over the next year, primarily driven by its expected two main drug clinical trials expenses.

For 2022, we expect a net loss of \$19 million and EPS of \$(1.63). For 2023, we expect a net loss of \$22 million and EPS of \$(1.83). The company estimates that the additional clinical and filing costs to advance CTx-1301 to a NDA filing (in late 2023) will be ~\$16.5 million. The company will also require additional funding for its other 2 drugs in development (CTx-1302 and CTx-2103).

We believe investors should be focused on its progress on its drug development, which will likely take at least several years before a potential FDA approval. Within the next year, the company plans to launch 2 Phase 3 and 1 Phase 1/2 trials and we should get Top-Line data from these studies.



Exhibit 22: Consensus Expectations (as of September 30, 2022)

	Revenue (mil)			EPS	
	<u>2022E</u>	<u>2023E</u>		<u>2022E</u>	<u>2023E</u>
Q1 Mar	\$0.0A		Q1 Mar	\$(0.44)A	
Q2 Jun	\$0.0A		Q2 Jun	\$(0.36)A	
Q3 Sep	\$0.0E		Q3 Sep	\$(0.36)E	
Q4 Dec	\$0.0E		Q4 Dec	\$(0.26)E	
Total	\$0.0E	\$0.0E	Total	\$(1.39)E	\$(1.07)E

*Quarterly estimates may not add to annual estimates due to variations in contributing estimates and rounding.

Source: Company report, Refinitiv, and Ascendiant Capital Markets estimates

Exhibit 23: Q2 2022 and Recent Corporate Highlights (as of August 11, 2022)

Werth Family Investment Associates Provides \$5 Million of Debt Financing

Cingulate received \$5 million of debt financing from Werth Family Investment Associates LLC (WFIA). The promissory note executed in favor of WFIA is unsecured with interest accruing at 15% per annum. Outstanding principal and interest is due and payable on August 8, 2025, and WFIA has a right during the first five business days of each calendar quarter beginning April 1, 2023 to call for payment 120 days after notice to the Company. WFIA owns 871,731 shares of Cingulate common stock and Peter J. Werth, a member of Cingulate's Board of Directors and the manager of WFIA, owns 21,849 shares of Cingulate common stock.

Scott Applebaum Appointed to Cingulate Board of Directors

Cingulate has expanded its Board of Directors to eight directors and appointed Scott Applebaum as a Class III director. Mr. Applebaum is an industry veteran with over 25 years of experience at large and small biopharmaceuticals companies. He is currently Chief Legal Officer and Corporate Secretary at VectivBio (NASDAQ:VECT), a biopharmaceutical company focused on the discovery, development, and commercialization of innovative treatments for severe rare conditions with high unmet medical need.

Clinical and Business Update

• **CTx-1301:** Cingulate has designed its clinical program for CTx-1301 (dexmethylphenidate), its lead investigational asset for the treatment of ADHD, based on FDA feedback regarding its CTx-1301 initial Pediatric Study Plan (iPSP), and longstanding guidance on the expedited approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

The Company has commenced study start-up activities for the CTx-1301 Phase 3, fixed-dose, pediatric and adolescent safety and efficacy study, and anticipates dosing the first patient in late 2022. Cingulate has been experiencing delays in the manufacturing and delivery of clinical supply for this study due to operational resource issues at its contract manufacturing organization. Manufacturing of the final two dosage strengths, which are necessary to dose the first patient, is expected to begin in the second half of this year. Results from the fixed-dose study are expected in the second half of 2023. In order to meet the pharmacology requirement for the CTx-1301 NDA submission, Cingulate plans to complete a food effect study in the fourth quarter of 2022. Assuming it receives positive clinical results from the Phase 3 trial and food effect study, Cingulate still plans to submit the NDA for CTx-1301 in late 2023 under the Section 505(b)(2) pathway.

In addition to the studies noted above, Cingulate plans to initiate an adult dose-optimization study (Phase 3b) to assess the onset and duration of efficacy in the second half of 2023. This Phase 3b trial is supplementary and is not required for the CTx-1301 NDA submission.

In order to achieve the filing of the NDA for CTX-1301 in late 2023 for potential FDA approval, Cingulate believes that it will need approximately \$16.5 million of additional capital. Cingulate will also need additional capital to advance its other programs. The Company is evaluating alternatives to raise additional capital, including equity and debt financing and non-dilutive strategic collaborations in the U.S. and abroad. In addition, Cingulate continues to evaluate commercial collaborations, which would provide more immediate access to marketing, sales, market access and distribution infrastructure.

• **CTx-1302:** Cingulate plans to initiate a Phase 1/2 bioavailability study in ADHD patients for CTx-1302 (dextroamphetamine), its second investigational asset for the treatment of ADHD, in 2023 and, if the results from this study are successful, the Company plans to initiate pivotal Phase 3 clinical trials in all patient segments for CTx-1302 in 2024 with results expected in 2025.

• **CTx-2103:** Cingulate announced in June the completion of the human formulation study for its third asset, CTx-2103, for the management of anxiety, which is the most common mental health concern in the U.S. Furthermore, this trial extends the potential of the PTR platform where multiple daily doses are required and the timing, style, and ratio of this medication delivery is paramount. The study was conducted at BDD Pharma in the United Kingdom. Results are expected later this month.

CTx-2103 contains the active pharmaceutical ingredient buspirone hydrochloride, a non-benzodiazepine medication, which has no evidence for the development or risk of dependency. However, due to its short half-life, buspirone is prescribed to be taken several times a day for management of anxiety, which can be challenging for patients and may lead to sub-optimal treatment outcomes. CTx-2103 will be designed as a once-daily, multi-dose tablet, which the Company believes will offer clear differentiation and compelling advantages over currently available treatment options.



We believe that the biggest potential variable in our financial model is the ability of the company to get FDA (or equivalent) approval for its CTx-1301 and CTx-1302 ADHD drugs under development. It is these approvals that are ultimately how Cingulate will be able to finally be able to generate revenue. If the company can make significant progress towards these goals, then revenue and earnings will likely be able to grow significantly. However, if the company has difficulties in making progress towards getting drug approvals, then revenue and profitability may not be achieved or will likely grow at a moderate rate or even not at all. Even after drug approvals, Cingulate faces a big challenge to successfully commercialize its products.

The company's balance sheet has \$8 million in cash and no debt as of June 2022. This does not include the recent \$5 million in debt (3 years at 15%) that it raised in August from a Board member (Peter Werth). In December 2021, the company had its IPO (initial public offering) selling 4.2 million shares at \$6.00 per share (raising ~\$25 million). We believe the company has enough cash through 2022, but we believe it will need to raise new capital in early 2023. The company has guided to having enough cash through Q1 2023.

Exhibit 24: Cingulate Financial Metrics

Recent Share Price (9/30/22)	\$ 1.07
52-Weeks Share Price (Low - High)	\$0.94 - 5.15
Shares Outstanding	11.4 million
Market Capitalization	\$12 million
Enterprise Value	\$4 million
Cash (6/30/22)	\$8 million
Debt (6/30/22)	\$0 million
2021A Revenue	\$0
2021A Net loss	\$21 million
2021A EPS	\$ (2.79)
2022E Revenue	\$0
2022E Net loss	\$19 million
2022E EPS	\$ (1.63)
2023E Revenue	\$0
2023E Net Ioss	\$22 million
2023E EPS	\$ (1.83)

Source: Company reports and Ascendiant Capital Markets estimates.



FINANCIAL MODEL

Income Statement (\$ mils)	2019	2020	Mar-21	Jun-21	Sep-21 Dec-21	2021	Mar-22	Jun-22	Sep-22	Dec-22	2022	Mar-23	Jun-23	Sep-23	Dec-23	2023
Fiscal Year End: December 31	FY-A	FY-A	Q1A	Q2A	-	FY-A	Q1A	Q2A	Q3E	Q4E	FY-E	Q1E	Q2E	Q3E	Q4E	FY-E
Total Revenue	0.0	0.0	0.0	0.0		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Cost of Revenues	0.0	0.0	0.0	0.0		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross Profit	0.0	0.0	0.0	0.0		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
											L					
Research & development	9.1	5.1	0.6	0.8		8.4	2.8	2.2	2.3	3.0	10.2	3.0	3.0	3.2	3.2	12.4
General and administrative	2.6	2.0	0.8	0.6		12.3	2.2	1.9	2.0	2.0	8.1	2.1	2.1	2.1	2.1	8.4
Restructuring and other	11.0	7.4	10			00.7	5.0	4.0	4.0	5.0	0.0	F 4	F 4	5.0	5.0	<u>0.0</u>
Total operating expenses	11.6	7.1	1.3	1.4		20.7	5.0	4.0	4.3	5.0	18.4	5.1	5.1	5.3	5.3	20.8
Operating income (loss)	(11.6)	(7.1)	(1.3)	(1.4)		(20.7)	(5.0)	(4.0)	(4.3)	(5.0)	(18.4)	(5.1)	(5.1)	(5.3)	(5.3)	(20.8)
Interest income (expense)	0.1	(0.1)	(0.0)	(0.0)		(0.0)	0.0	0.0	0.0	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.8)
Other income (expense)									0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Income before income taxes	(11.5)	(7.2)	(1.3)	(1.4)		(20.7)	(5.0)	(4.0)	(4.3)	(5.2)	(18.5)	(5.3)	(5.3)	(5.5)	(5.5)	(21.6)
Income taxes						0.0			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net income (loss)	(11.5)	(7.2)	(1.3)	(1.4)		(20.7)	(5.0)	(4.0)	(4.3)	(5.2)	(18.5)	(5.3)	(5.3)	(5.5)	(5.5)	(21.6)
Nonrecurring/noncash adjustme	ents					0.0					0.0					<u>0.0</u>
Net income (pro forma)	(11.5)	(7.2)	(1.3)	(1.4)		(20.7)	(5.0)	(4.0)	(4.3)	(5.2)	(18.5)	(5.3)	(5.3)	(5.5)	(5.5)	(21.6)
EBITDA																
Shares. Basic						7.4	11.3	11.3	11.4	11.5	11.4	11.6	11.7	11.8	11.9	11.8
Shares, Diluted						7.4	11.3	11.3	11.4	11.5	11.4	11.6	11.7	11.8	11.9	11.8
EPS Basic (pro forma)						(\$2.79)	(\$0.44)	(\$0.36)	(\$0.38)	(\$0.45)	(\$1.63)	(\$0.46)	(\$0.45)	(\$0.46)	(\$0.46)	(\$1.83)
EPS Diluted (pro forma)						(\$2.79)		· · ·	· · ·			· ·			(\$0.46)	
						(\$2.73)	(\$0.44)	(\$0.50)	(\$0.50)	(\$0.43)	(\$1.03)	(\$0.40)	(40.43)	(\$0.40)	(\$0.40)	(\$1.00)
Margins																
Gross margin																
Research & development																
General and administrative																
Operating margin																
Tax rate, GAAP																
Net margin																
Y/Y % change																
Total Revenue																
Gross margin																
Research & development		-44%				65%	391%				22%	9%	38%	39%	7%	21%
General and administrative		-22%				517%	193%				-34%	-7%		5%		3%
Operating income (loss)		-39%				192%	277%				-11%	2%	26%	23%		13%
Net income (loss)		-38%				188%	275%				-11%	6%	31%	28%		16%
EPS Diluted (pro forma)		#DIV/0!				-	#DIV/0!				-42%	3%	26%	23%		13%
Diatod (pro tornid)											/0	0,0	2070	2070	- /0	

Source: Company reports and Ascendiant Capital Markets estimates.



Cingulate Inc.

Balance Sheet (\$ mils)	Dec-19	Dec-20	Mar-21	Jun-21	Sep-21	Dec-21	Mar-22	Jun-22	Sep-22	Dec-22	Mar-23	Jun-23	Sep-23	Dec-23
Fiscal Year End: December 31	Q4A	Q4A			Q3A	Q4A	Q1A	Q2A	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
Assets														
Cash and cash equivalents	0.4	1.2			1.9	16.5	12.6	8.2	9.2	4.3	0.1	(4.9)	(10.1)	(15.3)
Short term investments	0.0	0.0			0.0	0.0	0.0		0.0	0.0	0.0	0.0	0.0	0.0
Deferred income taxes									0.0	0.0	0.0	0.0	0.0	0.0
Prepaid expenses and other	0.5	<u>0.6</u>			<u>3.6</u>	2.4	2.0	1.9	<u>1.9</u>	<u>1.9</u>	<u>1.9</u>	<u>1.9</u>	<u>1.9</u>	<u>1.9</u>
Total current assets	1.0	1.8			5.6	18.9	14.6	10.1	11.1	6.2	2.0	(3.0)	(8.2)	(13.4)
Property and equipment, net	3.0	3.0			2.6	3.1	3.1	3.0	2.9	2.8	2.7	2.6	2.5	2.4
Intangibles, net									0.0	0.0	0.0	0.0	0.0	0.0
Deferred income tax									0.0	0.0	0.0	0.0	0.0	0.0
Other	1.3	1.0			0.9	0.9	0.8	0.7	0.7	0.7	0.0	0.0	0.0	0.0
Total assets	5.3	5.8			9.1	22.9	18.4	13.8	14.7	9.7	4.7	(0.4)	(5.7)	(11.0)
Liabilities and stockholders' equity														
Accounts payable	1.9	1.0			0.9	0.3	0.6	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Accrued expenses	0.9	1.7			3.5	0.6	0.8	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Deferred income tax									0.0	0.0	0.0	0.0	0.0	0.0
Warrant liabilities									0.0	0.0	0.0	0.0	0.0	0.0
Other	0.2	0.2			0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Short term debt		0.5			0.4				0.0	0.0	0.0	0.0	0.0	0.0
Total current liabilities	3.0	3.4			5.1	1.2	1.6	0.9	0.9	0.9	0.9	0.9	0.9	0.9
Deferred income taxes									0.0	0.0	0.0	0.0	0.0	0.0
Warrant liabilities									0.0	0.0	0.0	0.0	0.0	0.0
Other long term liabilities	1.7	1.1			0.9	0.9	0.8	0.7	0.7	0.7	0.7	0.7	0.7	0.7
Long term debt									5.0	5.0	5.0	5.0	<u>5.0</u>	5.0
Total other liabilities	1.7	1.1			0.9	0.9	0.8	0.7	5.7	5.7	5.7	5.7	5.7	5.7
Common stock	0.6	32.3			0.0	0.0	0.0	0.0	0.2	0.4	0.6	0.8	1.0	1.2
Additional paid-in capital					52.2	72.6	72.8	73.0	73.0	73.0	73.0	73.0	73.0	73.0
Retained earnings		(31.0)			(49.1)	(51.7)	(56.7)	(60.8)	(65.1)	(70.3)	(75.6)	(80.8)	(86.3)	(91.8)
Other						. ,			0.0	0.0	0.0	0.0	0.0	0.0
Accumulated other comprehensive i	ncome	<u>0.0</u>				0.0	<u>(0.0)</u>	<u>(0.0)</u>	<u>(0.0)</u>	(0.0)	(0.0)	<u>(0.0)</u>	<u>(0.0)</u>	(0.0)
Total stockholders' equity	0.6	1.3			3.1	20.8	16.0	12.2	8.1	3.1	(2.0)	(7.0)	(12.3)	(17.6)
Total stockholders' equity and liab	ili 5.3	5.8			9.1	22.9	18.4	13.8	14.7	9.7	4.7	(0.4)	(5.7)	(11.0)

Balance Sheet Drivers

	Dec-21	Mar-22	Jun-22	Sep-22	Dec-22	Mar-23	Jun-23	Sep-23	Dec-23
	Q4A	Q1A	Q2A	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
Book & Cash Value (per share)									
Book Value per Share (diluted)	\$2.81	\$1.42	\$1.08	\$0.71	\$0.27	(\$0.17)	(\$0.60)	(\$1.04)	(\$1.48)
Cash per Share (diluted)	\$2.22	\$1.12	\$0.72	\$0.81	\$0.37	\$0.01	(\$0.42)	(\$0.86)	(\$1.28)
Net cash per Share (diluted)	\$2.22	\$1.12	\$0.72	\$0.37	(\$0.06)	(\$0.42)	(\$0.85)	(\$1.28)	(\$1.70)

Source: Company reports and Ascendiant Capital Markets estimates

Cingulate Inc. Cash Flow Statement (\$ mils) 2019

Cash Flow Statement (\$ mils)	2019	2020	Mar-21	Jun-21	Sep-21 Dec-21	2021	Mar-22	Jun-22	Sep-22	Dec-22	2022	Mar-23	Jun-23	Sep-23	Dec-23	2023
Fiscal Year End: December 31	FY-A	FY-A	Q1A	Q2A		FY-A	Q1A	Q2A	Q3E	Q4E	FY-E	Q1E	Q2E	Q3E	Q4E	FY-E
Cash flow from operating activit	ties															
Net income	(11.5)	(7.2)	(1.3)	(1.4)		(20.7)	(5.0)	(4.0)	(4.3)	(5.2)	(18.5)	(5.3)	(5.3)	(5.5)	(5.5)	· · ·
Depreciation	0.2	0.7	0.2	0.2		0.7	0.1	0.1	0.1	0.1	0.4	0.1	0.1	0.1	0.1	0.4
Amortization											0.0					0.0
Debt related amortization expen-	se										0.0					0.0
Stock comp						0.0	0.2	0.2	0.2	0.2	0.8	0.2	0.2	0.2	0.2	0.8
Deferred income taxes									0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Change in fair value of warrant li	iability										0.0					0.0
Writedowns and impairments											0.0					0.0
Other gains/losses											0.0					0.0
Other	(0.0)					12.7	(0.0)	0.0			0.0					0.0
Changes in operating assets and I																
Accounts receivable	(0.1)	(0.0)	(0.1)	(0.1)		(0.5)	0.0	0.5			0.6					0.0
Prepaid expenses & other curre	0.2	(0.0)	(0.2)	(1.0)		(1.3)	0.4	(0.5)			(0.1)					0.0
Income tax											0.0					0.0
Other assets	0.8	0.3	(0.0)	0.0		0.1	0.1	0.1	0.0	0.0	0.1	0.7	0.0	0.0	0.0	0.7
Accounts payable	1.7	(0.4)	(0.3)	0.8		(1.3)	0.4	(0.7)			(0.3)					0.0
Accrued expenses						0.1					0.0					0.0
Other liabilities	<u>(0.7)</u>	<u>(0.1)</u>	<u>0.0</u>	<u>(0.1)</u>		<u>(0.3)</u>	<u>(0.1)</u>	<u>(0.1)</u>	0.0	0.0	<u>(0.1)</u>	0.0	0.0	0.0	0.0	0.0
Net cash (used in) provided by	(9.5)	(6.8)	(1.7)	(1.6)		(10.4)	(3.9)	(4.4)	(4.0)	(4.9)	(17.1)	(4.2)	(5.0)	(5.2)	(5.2)	(19.6)
Cash flow from investing activit	ies															
Purchases of property and equi	(1.0)	(0.4)	(0.1)	(0.0)		(0.8)	(0.0)		(0.0)	0.0	(0.0)	(0.0)	0.0	(0.0)	(0.0)	(0.0)
Purchases of short-term investn	3.8	0.0						0.0			0.0					0.0
Acquisitions											0.0					0.0
Other								<u>(0.0)</u>			<u>(0.0)</u>					0.0
Net cash used in investing activ	2.7	(0.4)	(0.1)	(0.0)		(0.8)	(0.0)	(0.0)	(0.0)	0.0	(0.0)	(0.0)	0.0	(0.0)	(0.0)	(0.0)
Cash flow from financing activit	ies															
Issuance of debt		1.0	0.1	(0.1)					5.0	0.0	5.0	0.0	0.0	0.0	0.0	0.0
Repayment of debt		(0.5)	(0.1)	(0.1)		(0.9)	(0.0)	(0.0)			(0.0)					0.0
Issuance of stock	6.1	7.5	1.4	2.0		27.5			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from stock option exe	rcises										0.0					0.0
Other											0.0					0.0
Dividends and distributions											0.0					0.0
Cash provided by (used in) fina	6.1	8.0	1.4	1.8		26.5	(0.0)	(0.0)	5.0	0.0	5.0	0.0	0.0	0.0	0.0	0.0
Effect of exchange rate on cash	0.0	0.0	0.0	0.0		0.0	0.0	0.0			0.0					0.0
				• -												
Net increase (decrease) in cash	(0.6)	0.8	(0.4)	0.2		15.3	(3.9)	(4.4)	1.0	(4.9)	(12.2)	(4.2)	(5.0)	(5.2)	(5.2)	
Beginning cash and equivalents	1.1	0.4	1.2	0.8		1.2	16.5	12.6	8.2	9.2	16.5	4.3	0.1	(4.9)	(10.1)	
Ending cash and equivalents Source: Company reports and Asce	0.4	1.2	0.8	1.0		16.5	12.6	8.2	9.2	4.3	4.3	0.1	(4.9)	(10.1)	(15.3)	(15.3)

Source: Company reports and Ascendiant Capital Markets estimates



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Cingulate Inc.

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Total return is defined as price appreciation plus dividend yield.

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Total return is defined as price appreciation plus dividend yield.

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			Banking Services 2 months	
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Total	42	100%	15	36%

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