Cytokinetics, Inc. (NASDAQ: CYTK)

Aparna Vagvala, Siena Verprauskus, Aurian Azghandi, Nicolas Tchkotoua, Noor Kaur, and Eli Soffer

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Company and Product Overview

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Company Overview

Business

- Cytokinetics was founded in 1997 in San Francisco as a small biotech start-up with broad focus in musculoskeletal weakness
- CYTK went public in 2004, having narrowed its focus to heart failure and ALS therapies
- One of CYTK's flagship drugs, Omecamtiv, has been in development alongside Amgen ($AMGN) since 2006, under a financing agreement to commercialize Omecamtiv; Amgen did not re-up the agreement in 2020, a negative sign
- CYTK abandoned ALS in favor of another heart failure drug, Aficamten; both Aficamten and Omecamtiv are currently in P3

Leadership

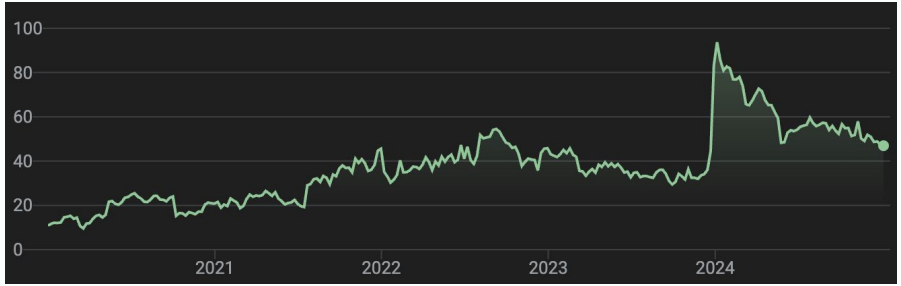
- Robert I. Blum (President and CEO):
  - Appointed President and CEO in 2007, has been with Cytokinetics since 1998.
  - Previously held senior positions at COR Therapeutics and Marion Laboratories.
  - B.A., Human Biology and Economics from Stanford University; M.B.A. from HBS
- John T. Henderson, M.D. (Chairman of the Board):
  - Appointed Chairman in April 2022, has been a Director since 2009.
  - Former Vice President at Pfizer Pharmaceuticals Group, with experience in R&D.
  - B.S. Biology & M.D. from University of Edinburgh
- Ching W. Jaw (Chief Financial Officer):
  - Joined Cytokinetics as CFO in June 2017.
  - B.S., MechE, from National Taiwan University; M.B.A. from UChicago Booth

Company Overview (Cont.)

Management Problems

- Rocky road: Since the (very) successful Aficamten phase 3 clinical trial (Dec ‘23), CYTK stock price has tumbled with diminished market confidence that management will pursue a sale
- This was accelerated in May ‘24 with a new complicated royalty financing agreement which is seen as an impediment to a sale

Price



Financials

Run-rate Operating Expenses	$570mn, with $110mn SBC + D&A
Cash & Equivs. on Balance Sheet	$1.3bn, with access to $350mn incremental TL
Net Cash:	$625mn
Stock Price	$47.21
Market Cap	$5.57bn

Drug Overview – Aficamten

Hypertrophic Cardiomyopathy

- HCM is characterized by abnormal thickening of the heart muscle, specifically the walls of the left ventricle.
- This leads to reduced compliance and an impaired ability of the heart to relax, thereby affecting the overall cardiac output.
- Patients often experience symptoms such as breathlessness, fatigue, chest pain, and, in severe cases, sudden cardiac death.

Use Case

- **Dosage:** Aficamten is administered orally, with dosing tailored based on patient response and clinical trial findings.
- **Indications:** It is used for symptomatic relief and disease modification in HCM patients. Doctors administer Aficamten to reduce outflow tract obstruction and improve quality of life, particularly in cases where standard treatments fail or are insufficient.

Insider, US Census Bureau

Drug Overview – Aficamten

Clinical Trials

- **Phase 2 – REDWOOD-HCM:**
  - Reduced heart stress and improved patient symptoms.
  - No serious side effects like irregular heart rhythms.
- **Phase 3 – SEQUOIA-HCM:**
  - Improved heart efficiency, energy levels, and quality of life.
  - Fewer surgeries needed; low risk of complications.
- **Ongoing Studies:**
  - Exploring long-term benefits like fewer hospital visits.

Efficacy – Our View

- Aficamten is set to become the go-to treatment for HCM. It helps patients feel better, live more actively, and avoids unnecessary risks or surgeries, all while keeping the heart safe.

Insider, US Census Bureau

Drug Overview – Omecamtiv

Heart Failure

- Heart failure with reduced ejection fraction or HFrEF is defined by
- **decreased** systolic function (how the heart contracts and pumps out blood to the rest of the body)
- → **reduced** cardiac output (quantity of blood pumped)
- → **increased** filling pressure (pressure measurement in the heart which determines the volume of blood pumped–stroke volume).
- Omecamtiv activates the motor protein responsible for heart muscle contraction, and attempts to increase the heart's systolic function without causing arrhythmias

Use Case

- Taken through an oral tablet of 25-100mg once daily
- Used when LVEF (Left ventricular ejection fraction) < 40%
    - Approximately 2 million people in the U.S. are estimated to have an ejection fraction ≤30%, indicating they may have worsening heart failure
- Used for patients who don't respond to current treatments like ACE inhibitors, beta-blockers, or ARBs

Drug Overview – Omecamtiv

Clinical Trials

- COSMIC-HF Trial (2021)
  - (+) The drug significantly improved left ventricular ejection fraction (LVEF) and had a favorable impact on exercise capacity and other markers of heart failure.
  - Some evidence of a reduction in the risk of heart failure hospitalizations.
- GALACTIC-HF Trial (2020)
  - (+) A reduction in the risk of heart failure hospitalizations and a modest improvement in the time to first heart failure event (such as hospitalization or death).
  - No statistically significant reduction in overall mortality. → FDA rejected the drug in February 2023

Efficacy – Our View

- Despite FDA rejection, Trials have positive and promising results
- "Frankly, many of our investors are more interested in [**HCM**] than heart failure just given that it's an area that **is emerging as a stronger economic opportunity for us**," Fady Malik, head of R&D for Cytokinetics, in an interview ahead of the FDA decision.
- Demand for a Heart Failure Solution Persists
  - 65 million people affected and approximately 50% of people diagnosed with heart failure will die within five years of initial hospitalization → despite being treated with available guideline-directed medical therapies, people with worsening heart failure remain at high risk for heart failure events and hospitalization. → GALACTIC addresses this
  - "If approved by the FDA, omecamtiv mecarbil will become the first therapy indicated for HFrEF that directly targets the mechanisms of the heart responsible for contraction – or its pumping function."
  - Dec 3rd 2024 - Comet Phase 3 Trial Announced

Drug Overview – CK-586

HFpEF

- CK-586 is being developed for **Heart Failure with Preserved Ejection Fraction (HFpEF)**.
- HFpEF affects approximately half of all heart failure patients, and its prevalence is growing globally.
- This disease is characterized by the heart's inability to relax and fill properly, resulting in symptoms like breathlessness, fatigue, and fluid retention.
- Approximately 75% of HFpEF patients die within five years of initial hospitalization, highlighting the need for new treatments.

Use Case

- CK-586- is administered orally and selectively inhibits cardiac myosin ATPase activity at the sarcomere level
- Requires the presence of the regulatory light chain (RLC) in myosin dimers for its inhibitory action
- Reduces hypercontractility by decreasing active myosin cross-bridges during contraction without impacting calcium transients.
- Demonstrated improved lusitropy in preclinical models, supporting its development for HFpEF, particularly in patients exhibiting hypercontractility and ventricular hypertrophy.

Insider, US Census Bureau

Drug Overview – CK-586

Clinical Trials

Phase 1 Design and Key Findings

- **Design:** A double-blind, placebo-controlled study evaluating safety, tolerability, and pharmacokinetics of CK-586 in healthy participants. It included:
  - Seven single ascending dose cohorts (10 mg to 600 mg).
  - Two multiple-dose cohorts (100 mg and 200 mg once daily for 7 days).
- **Results:**
  - CK-586 was safe and well-tolerated, with no serious adverse events.
  - Demonstrated dose-linearity and a half-life of 14-17 hours, achieving steady-state concentrations within seven days.
  - Exposure-dependent reductions in left ventricular ejection fraction (LVEF), with an average decrease of <5% at the highest single dose (600 mg).
- These results support the potential for once-daily fixed-dose administration.

Next Steps

Phase 2

Objective:

- Evaluate the efficacy and safety of CK-586 in patients with HFpEF exhibiting hypercontractility and ventricular hypertrophy.

Design:

- Randomized, placebo-controlled study to assess the impact on cardiac function and clinical outcomes.

Timeline:

- Initiation expected in Q4 2024.

Investment Thesis

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Investment Thesis Summary

Strong safety profiles

- Minimal acute adverse side effects for life-threatening diseases is rare and valuable
- Will enhance uptake, and mitigates jump risk on all pharma companies of lawsuits down the line

Effective, life-saving therapies

- Omecamtiv denied accelerated approval timeline, which agitated investor sentiment
- Clinical trial results show statistically significant & *clinically meaningful* results – Aficamten and Omecamtiv are set to be the standard of care in the HCM and Heart Failure space

Overblown management concerns

- Concerns over management malaise towards a sale process, the most common route for late-stage biotechs, weighs on share price. We believe market view on "irrational" management is overblown, with strong incentive compensation schemes

Overall, strong and de-risked commercialization prospects for U.S. Aficamten alone support the current stagnant share price, with significant upside if and when Omecamtiv is approved; our thesis requires no valuation support from the pipeline drug, while we have them continuing to burn cash on R&D, nor international commercialization from Aficamten or Omecamtiv, or post-patent expiration residual value

Millennials Are More Likely to Buy Given Falling Interest Rates

Safety Profile

- The safety profile of omecamtiv mecarbil in clinical trials has generally been well-tolerated, with the most common side effects being mild, including headache, dizziness, and nausea. No major safety concerns related to arrhythmias or worsening heart failure have been identified
- Clinical trials of Aficamten showed no significant cardiac side effects, such as arrhythmias or impaired systolic function.

Efficacy:

- **Omecamtiv Symptom Relief:** Improvement in LVEF (Left Ventricular Ejection Fraction) and reduction in primary outcome events
- **Disease Modification & Patient Outcomes:** Directly improving the heart's ability to contract removes the risk posed by other drugs that address symptoms rather than the root cause
- **Clinical Impact:** Galactic HF trial showed improvements in patients who were taking the existing drugs on the market → we have confidence that the new COMET Phase 3 Trial will yield positive results

- **Aficamten Symptom Relief:** Significant reduction in heart stress and symptoms like fatigue and breathlessness.
- **Disease Modification:** Sustained improvements in heart function reduce the need for invasive procedures.
- **Patient Outcomes:** Enhanced quality of life and potential for fewer hospitalizations.
- **Clinical Impact:** Positioned as the standard of care for HCM due to its safety, convenience, and effectiveness.

Management Concerns

- It is generally expected that late-stage biotechnology companies will sell their assets pre-commercialization, return capital to shareholders, and potentially retain some money to continue developing pipeline drugs – this is due to commercialization synergies necessarily found in larger pharmaceutical companies with experience hiring sales teams, going to market, international expansion, etc.
- The CEO shot down all takeout rumors in the 4Q23 earnings call, and the latest royalty renegotiation with Royalty Pharma is seen as destructive to CYTK's takeout profile
- We believe there are several mitigating factors here:
    - Incentive compensation plans: the CEO owns $20mn of CYTK, 90% of '23 total compensation is non-salary
    - Commercial EVP's 3-year tenure, predating P3 trials, now boasting a 25 person team, indicates sufficient pre-planning to commercialization which will boost acquisition as well as standalone value to any investor
    - Generally, we believe in Blum's dedication to shareholder value and his capability to make the correct capital allocation decisions – he has a strong background which would allow him to land as an executive at other pharma companies, de-risking his career in the event of a sale, alongside sufficient financial incentive

Valuation

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Valuation Summary

Case 1: Probability Adjusted (Base) - 162% upside

- Using probability adjusted cash flows based on 85% Aficamten POS, 40% Omecamtiv POS
- 25% of market captured for each drug at peak, 5 years from approval date

Case 2: Both pass: 700% upside

- Both drugs pass FDA approval and are commercialized, Aficamten in 1 year, Omecamtiv in 2 years
- Revenues recognized from both Omecamtiv and Aficamten

Case 3: Aficamten passes, other fails: 274% upside

- Only Aficamten reaches approval, but Omecamtiv does not pass
- Revenues only recognized from Aficamten as Omecamtiv cannot be sold

Valuation Summary

Major Drivers

- Pricing
  - Aficamten: $100K at Year 1
  - Omecamtiv: $21.9K at Year 1
- Probability of Success
  - 40% approval rate of Omecamtiv
  - 85% approval rate of Aficamten
- Peak market share for each drug
  - time to peak of 5 years
  - implied peak sales at 25% market share

Key Inputs

- WACC
- TAM – patient population
  - Aficamten: 0.2% of US Population
  - Omecamtiv: 1.5% of US Population

Case 1 - Probability Weighted

Revenue Build for CYTK - Both Succeed	*2020A*	*2021A*	*2022A*	*2023A*	*2024E*	*2025E*	*2026E*	*2027E*	*2028E*	*2029E*	*2030E*	*2031E*	*2032E*	*2033E*
Research and development revenues, mm	$ 17	$ 11	$ 7	$ 4	$ 2	$ 1	$ 1	$ 1	$ 1	$ 0	$ 0	$ 0	$ 0	$ 0
Y/Y Research and development revenues growth, %	*-38.50%*	*-35.76%*	*-37.70%*	*-38.80%*	*-56.81%*	*-17.12%*	*-25.72%*	*-28.00%*	*-32.50%*	*-10.00%*	*-10.00%*	*-10.00%*	*-10.00%*	*-10.00%*
% R&D Expenditures			2.75%	1.21%	1.21%	1.21%	1%	0.80%	0.60%	0.60%	0.60%	0.60%	0.60%	0.60%
License revenues, mm	$ 37	$ 55												
Y/Y License revenues growth, %		*50.41%*												
Milestone revenues, mm	$ 3	$ 5	$ 1	$ 4										
Y/Y Milestone revenues growth, %		*78.57%*	*-80.00%*	*250.00%*										
Aficamten net sales														
HCM prevalence -- USA	*0.20%*	*0.20%*	*0.20%*	*0.20%*	*0.20%*	*0.20%*	*0.20%*	*0.20%*	*0.20%*	*0.20%*	*0.20%*	*0.20%*	*0.20%*	*0.20%*
Hypertrophic cardiomyopathy patient population	*669,800*	*671,475*	*673,153*	*674,836*	*676,523*	*678,214*	*679,910*	*681,610*	*683,314*	*685,022*	*686,735*	*688,451*	*690,173*	*691,898*
% of population receiving treatment	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
% market captured	0.0%	0.0%	0.0%	0.0%	0.0%	5.0%	7.5%	12.5%	20.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Patients Treated	0	0	0	0	0	28,824	43,344	72,421	116,163	145,567	145,931	146,296	146,662	147,028
Treatment Price (est. per year)						$ 100,000	$ 105,120	$ 110,502	$ 116,160	$ 122,107	$ 128,359	$ 134,931	$ 141,840	$ 149,102
Total Aficamten sales, mm	$ -	$ -	$ -	$ -	$ -	$ 2,882	$ 4,556	$ 8,003	$ 13,494	$ 17,775	$ 18,732	$ 19,740	$ 20,802	$ 21,922
Royalties					$ -	$ (130)	$ (205)	$ (360)	$ (607)	$ (800)	$ (843)	$ (888)	$ (936)	$ (986)
Total Aficamten revenue, mm					**$ -**	**$ 2,753**	**$ 4,351**	**$ 7,643**	**$ 12,886**	**$ 16,975**	**$ 17,889**	**$ 18,852**	**$ 19,866**	**$ 20,936**
Omecamtiv Mecarbil net sales														
Left ventricular systolic heart failure prevalence -- USA	*1.50%*	*1.50%*	*1.50%*	*1.50%*	*1.50%*	*1.50%*	*1.50%*	*1.50%*	*1.50%*	*1.50%*	*1.50%*	*1.50%*	*1.50%*	*1.50%*
Left ventricular systolic heart failure patient population	*5,023,500*	*5,036,059*	*5,048,649*	*5,061,271*	*5,073,924*	*5,086,609*	*5,099,325*	*5,112,073*	*5,124,854*	*5,137,666*	*5,150,510*	*5,163,386*	*5,176,295*	*5,189,235*
% of population receiving treatment	70.0%	70.0%	70.0%	70.0%	70.0%	70.0%	70.0%	70.0%	70.0%	70.0%	70.0%	70.0%	70.0%	70.0%
% market captured	0.0%	0.0%	0.0%	0.0%	0.0%	0.00%	5.0%	7.5%	12.5%	20.0%	25.0%	25.0%	25.0%	25.0%
Patients Treated	0	0	0	0	0	0	178,476	268,384	448,425	719,273	901,339	903,593	905,852	908,116
Treatment Price (est. per year)						$ -	$ 21,900	$ 23,021	$ 24,200	$ 25,439	$ 26,741	$ 28,111	$ 29,550	$ 31,063
Total Omecamtive sales, mm	$ -	$ -	$ -	$ -	$ -	$ -	$ 3,909	$ 6,179	$ 10,852	$ 18,298	$ 24,103	$ 25,401	$ 26,768	$ 28,209
Royalties					$ -	$ -	$ (176)	$ (278)	$ (488)	$ (823)	$ (1,085)	$ (1,143)	$ (1,205)	$ (1,269)
Total Omecamtiv revenue, mm					**$ -**	**$ -**	**$ 3,733**	**$ 5,901**	**$ 10,364**	**$ 17,474**	**$ 23,019**	**$ 24,258**	**$ 25,563**	**$ 26,939**
Total revenue, mm	**$ 56**	**$ 71**	**$ 8**	**$ 8**	**$ 2**	**$ 2,754**	**$ 8,085**	**$ 13,544**	**$ 23,250**	**$ 34,450**	**$ 40,908**	**$ 43,110**	**$ 45,430**	**$ 47,875**
Y/Y Total revenue growth, %		26.34%	-89.22%	-1.32%	-76.96%	159315%	193.56%	67.52%	71.67%	48.17%	18.75%	5.38%	5.38%	5.38%

Case 1 - Probability Weighted

Unlevered Free Cash Flow	*2020A*	*2021A*	*2022A*	*2023A*	*2024E*	*2025E*	*2026E*	*2027E*	*2028E*	*2029E*	*2030E*	*2031E*	*2032E*	*2033E*
EBIT		$	(324)	$ (496)	$ (319)	$ 1,259	$ 2,070	$ 3,726	$ 6,357	$ 8,410	$ 8,875	$ 9,363	$ 9,877	$ 10,417
Less: adjusted taxes		$	-	$ -	$ -	$ (264)	$ (435)	$ (782)	$ (1,335)	$ (1,766)	$ (1,864)	$ (1,966)	$ (2,074)	$ (2,188)
Less: capex		$	(10)	$ (20)	$ (15)	$ (15)	$ (15)	$ (15)	$ (15)	$ (15)	$ (15)	$ (15)	$ (15)	$ (15)
Plus: D&A		$	6	$ 12	$ 0	$ 83	$ 131	$ 229	$ 387	$ 509	$ 537	$ 566	$ 596	$ 628
Less: increases in working capital		$	-	$ -	$ (2)	$ (2)	$ (87)	$ (153)	$ (258)	$ (340)	$ (358)	$ (377)	$ (397)	$ (419)
Unlevered FCF		**$**	**(328)**	**$ (504)**	**$ (336)**	**$ 1,060**	**$ 1,664**	**$ 3,005**	**$ 5,136**	**$ 6,799**	**$ 7,175**	**$ 7,570**	**$ 7,986**	**$ 8,424**
Clinical Phase of Aficamten		Phase 2		Phase 3	Phase 3	Phase 3	Approved	Approved	Approved	Approved	Approved	Approved	Approved	Approved
Probability of cash flows			100.0%	100.0%	100.0%	100.0%	100%	100%	100%	100%	100%	100%	100%	100%
Prob-adjusted FCF		$	(328)	$ (504)	$ (336)	$ 1,060	$ 1,664	$ 3,005	$ 5,136	$ 6,799	$ 7,175	$ 7,570	$ 7,986	$ 8,424
Clinical Phase of Omecamtiv		Regulatory Review		Phase 3	Phase 3	Approved	Approved	Approved	Approved	Approved	Approved	936317.4%	987680.7%	1041712.5%
Probability of cash flows			100.0%	100.0%	60.0%	60.0%	60%	60%	60%	60%	60%	60%	60%	60%
Prob-adjusted FCF		$	(328)	$ (504)	$ (202)	$ 636	$ 998	$ 1,803	$ 3,082	$ 4,079	$ 4,305	$ 4,542	$ 4,792	$ 5,054
Years					1	2	3	4	5	6	7	8	9	10
Discount rate			12.0%	12.0%	12.0%	12.0%	12.0%	12.0%	12.0%	12.0%	12.0%	12.0%	12.0%	12.0%
Discount factor			1.00	1.00	0.89	0.80	0.71	0.64	0.57	0.51	0.45	0.40	0.36	0.32
Present value of cash flows		**$**	**(328)**	**$ (504)**	**$ (300)**	**$ 845**	**$ 1,184**	**$ 1,910**	**$ 2,914**	**$ 3,444**	**$ 3,246**	**$ 3,058**	**$ 2,880**	**$ 2,712**

Case 1 - Probability Weighted

DCF		
Sum of discounted cash flows	$	14,769.21
Terminal value	$	-
Present value of terminal value	$	-
Enterprise value	$	14,769.21
Plus: net cash		
Market cap	$	14,769.21
Shares outstanding (in millions)		118
Price per share	**$**	**125.16**
Current Price	$	47.68
Upside		162.51%

Case 2 - Both Succeed

Case 2: Both Succeed

DCF		
Sum of discounted cash flows	$	45,054.14
Terminal value	$	-
Present value of terminal value	$	-
Enterprise value	$	45,054.14
Plus: net cash		
Market cap	$	45,054.14
Shares outstanding (in millions)		118
Price per share	**$**	**381.81**
Current Price	$	47.68
Upside		700.79%

Case 3 - Aficamten Only

Case 2: Both Succeed

DCF		
Sum of discounted cash flows	$	21,061.12
Terminal value	$	-
Present value of terminal value	$	-
Enterprise value	$	21,061.12
Plus: net cash		
Market cap	$	21,061.12
Shares outstanding (in millions)		118
Price per share	**$**	**178.48**
Current Price	$	47.68
Upside		274.34%

Appendix

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Catalyst path

Aficamten

- **Report topline results from MAPLE-HCM** in 1H 2025
- **Complete enrollment of ACACIA-HCM** in 2025
- **Continue enrollment of CEDAR-HCM** in 2024
- **Continue Phase 1 study of *aficamten* in healthy Japanese volunteers** in 2024

Omecamtiv Mecarbil

- **Continue enrollment of COMET-HF** in 2024

CK-586

- **Initiate AMBER-HFpEF** in Q4 2024

Weighting of Unlevered Free Cash flows

Unlevered Free Cash Flow	*2020A*	*2021A*	*2022A*	*2023A*	*2024E*	*2025E*	*2026E*	*2027E*	*2028E*	*2029E*	*2030E*	*2031E*	*2032E*	*2033E*
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Less: adjusted taxes		$	-	$ -	$ -	$ (264)	$ (435)	$ (782)	$ (1,335)	$ (1,766)	$ (1,864)	$ (1,966)	$ (2,074)	$ (2,188)
Less: capex		$	(10)	$ (20)	$ (15)	$ (15)	$ (15)	$ (15)	$ (15)	$ (15)	$ (15)	$ (15)	$ (15)	$ (15)
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Discount rate			12.0%	12.0%	12.0%	12.0%	12.0%	12.0%	12.0%	12.0%	12.0%	12.0%	12.0%	12.0%
Discount factor			1.00	1.00	0.89	0.80	0.71	0.64	0.57	0.51	0.45	0.40	0.36	0.32
Present value of cash flows		**$**	**(328)**	**$ (504)**	**$ (300)**	**$ 845**	**$ 1,184**	**$ 1,910**	**$ 2,914**	**$ 3,444**	**$ 3,246**	**$ 3,058**	**$ 2,880**	**$ 2,712**