



**There's a lot  
in this.**

# Before this single pill gets to the pharmacy, it requires:

- Identification of product opportunities
- Due diligence and in-licensing
- Pre-clinical studies
- Clinical and commercial manufacturing
- Multiple clinical trials
- Significant regulatory work
- Intellectual property know-how
- Finding great partners

And that's not all. At Cipher, we have worked hard to build the capabilities necessary to find, develop and commercialize improved versions of current drugs. We believe we have a valuable foundation and one that is built for sustainable success.

54

Clinical Trials

5

New Drug Applications

3

Licensing Partnerships

15

Experienced Staff

2

Final FDA Approvals

1

Growing Royalty Stream

That's a lot.



## Letter to Shareholders

The first quarter of 2010 was highlighted by continued growth in weekly prescriptions of Lipofen<sup>®</sup>, which drove a strong year-over-year increase in our revenue and enabled us to narrow our operating loss. While the U.S. fenofibrate market remains highly competitive, new Lipofen<sup>®</sup> prescriptions have grown solidly in recent quarters. Over the past three months, for example, new prescriptions and total prescriptions rose by 26% and 16%, respectively. This growth has been driven by increased promotion and sales force expansion at Kowa, our U.S. marketing partner.

In Q1 2010, we continued to make good progress with the pivotal Phase III safety study of CIP-ISOTRETINOIN, our acne medication. From 176 patients at year end, we crossed the 50% enrollment milestone of 400 patients at the end of the quarter, resulting in a US\$2.0 million milestone payment from our marketing partner. Current enrollment is now well over 500 patients and we are on track to complete enrollment this year. We continue to feel strongly that as a first-in-class, best-in-class product, CIP-ISOTRETINOIN has tremendous market potential.

We also had an important development in the first quarter with our extended-release tramadol product, when we received a favourable judgment in pending patent litigation, removing any further stay of FDA approval. Subsequently, we received final FDA approval for CIP-TRAMADOL ER for the treatment of moderate to moderately severe chronic pain in adults. This represents our second FDA approval—a major achievement for the Company that reflects a significant amount of effort and dedication from our team, led by Dr. Jason Gross. We believe our product's unique capsule formulation comprising an immediate-release tablet and sustained-release beads, combined with having no food effect, will make it an attractive alternative for clinicians and chronic pain sufferers.

We are currently preparing for the U.S. commercial launch of the product, which includes securing a marketing partner and finalizing commercial manufacturing requirements. The actual timing of the launch will also be influenced by the outcome of the appeal filed by Purdue Pharma Products L.P. against Par Pharmaceutical, Inc., which relates to the Orange Book-listed patents for Ultram<sup>®</sup> ER, the reference product in Cipher's New Drug Application. A decision in that case is not expected until late 2010.

Consistent with our strategy to expand the markets for our current products, we also announced that our new drug submission to the Health Canada was accepted for review during the first quarter, and we expect the review to be completed by early 2011.

### *Financial Review*

Total revenue in Q1 2010 was \$0.9 million, compared with \$0.6 million in Q1 2009. The improved performance reflects the continued market penetration by Lipofen<sup>®</sup> as Kowa increases the sales and promotion effort behind the product.

Gross Research and Development ("R&D") expenditures for Q1 2010 rose to \$4.1 million, compared with \$0.3 million in Q1 2009, driven by the CIP-ISOTRETINOIN clinical study. The reported R&D expenditure amount of \$0.3 million for Q1 2010 is net of \$3.8 million of reimbursed expenses by our U.S. marketing partner. Operating, General and Administrative expenses for Q1 2010 were \$1.0 million, consistent with the prior year. The loss for the three

months ended March 31, 2010 decreased to \$0.5 million (\$0.02 per basic and diluted share), compared with a net loss of \$0.8 million (\$0.03 per basic and diluted share) in Q1 2009.

Our financial position remained solid at quarter-end. As at March 31, 2010, Cipher had cash of \$9.1 million, compared with \$9.0 million as at December 31, 2009.

Looking ahead, we have several priorities in 2010.

- Working closely with Kowa as it expands its sales force further and we see the full impact of this increased sales and marketing effort. We are expecting to achieve a US\$1.0 million milestone payment by Q3 of this year;
- Completing trial enrollment for CIP-ISOTRETINOIN;
- Securing a marketing partner for our extended-release tramadol and preparing for commercialization; and
- Expanding our pipeline with novel products.

We look forward to updating you on our progress against these at the end of the second quarter.

Sincerely,

A handwritten signature in cursive script that reads "Larry Andrews".

Larry Andrews  
President and Chief Executive Officer

## **MANAGEMENT'S DISCUSSION AND ANALYSIS**

### **MARCH 31, 2010**

The following is a discussion and analysis of the operating results and financial position of Cipher Pharmaceuticals Inc. ("Cipher" or "the Company") for the three months ended March 31, 2010. This document should be read in conjunction with the unaudited financial statements and the accompanying notes, which have been prepared in accordance with Canadian generally accepted accounting principles ("GAAP"). Additional information about the Company, including the audited financial statements, MD&A and Annual Information Form for the year ended December 31, 2009, is available on SEDAR at [www.sedar.com](http://www.sedar.com).

The discussion and analysis within this MD&A are as of April 22, 2010.

#### **CAUTION REGARDING FORWARD-LOOKING STATEMENTS:**

This document includes forward-looking statements within the meaning of certain securities laws, including the "safe harbour" provisions of the Securities Act (Ontario) and other provincial securities law in Canada. These forward-looking statements include, among others, statements with respect to our objectives, goals and strategies to achieve those objectives and goals, as well as statements with respect to our beliefs, plans, objectives, expectations, anticipations, estimates and intentions. The words "may", "will", "could", "should", "would", "suspect", "outlook", "believe", "plan", "anticipate", "estimate", "expect", "intend", "forecast", "objective", "hope" and "continue" (or the negative thereof), and words and expressions of similar import, are intended to identify forward-looking statements.

By their very nature, forward-looking statements involve inherent risks and uncertainties, both general and specific, which give rise to the possibility that predictions, forecasts, projections and other forward-looking statements will not be achieved. Certain material factors or assumptions are applied in making forward-looking statements and actual results may differ materially from those expressed or implied in such statements. We caution readers not to place undue reliance on these statements as a number of important factors, many of which are beyond our control, could cause our actual results to differ materially from the beliefs, plans, objectives, expectations, anticipations, estimates and intentions expressed in such forward-looking statements. These factors include, but are not limited to, the applicability of patents and proprietary technology; possible patent litigation; regulatory approval of products in the Company's pipeline; changes in government regulation or regulatory approval processes; government and third-party payer reimbursement; dependence on strategic partnerships for product candidates and technologies, marketing and research and development ("R&D") services; meeting projected drug development timelines and goals; intensifying competition; rapid technological change in the pharmaceutical industry; anticipated future losses; the ability to access capital to fund R&D; and the ability to attract and retain key personnel.

We caution that the foregoing list of important factors that may affect future results is not exhaustive. When reviewing our forward-looking statements, investors and others should carefully consider the foregoing factors and other uncertainties and potential events. Additional information about factors that may cause actual results to differ materially from expectations, and about material factors or assumptions applied in making forward-looking statements, may be found in the "Risk Factors" section of our Annual Information Form, under "Business Risks" and elsewhere in the following Management's Discussion and Analysis of Operating Results and Financial Position and elsewhere in our filings with Canadian securities regulators. Except as required by Canadian securities law, we do not undertake to update any forward-looking statements, whether written or oral, that may be made from time to time by us or on our behalf; such statements speak only as of the date made. The forward-looking statements included herein are expressly qualified in their entirety by this cautionary language.

## OVERVIEW:

Cipher is a drug development company focused on commercializing novel formulations of successful, currently marketed molecules using advanced drug delivery technologies. Cipher's strategy is to in-license products that incorporate innovative drug delivery technologies and advance them through the clinical development and regulatory approval stages, after which the products will be out-licensed to international partners. Because Cipher's products are based on proven technology platforms applied to currently marketed drugs, they are expected to have lower approval risk, shorter development timelines and significantly lower development costs.

The Company seeks to create relationships with partners that provide both proven technology and manufacturing capabilities. Cipher believes that its internal clinical and regulatory capabilities combined with the proven technology and manufacturing strength of its intended partners will result in successful commercial products and will allow the Company to manage the risks associated with the drug development industry. The Company's regulatory strategy is to take the more rapid U.S. Food and Drug Administration ("FDA") 505(b)(2) approach to achieving approval for a New Drug Application ("NDA"). This approach allows the Company to rely on the significant amount of efficacy and safety data already filed with the FDA, thereby reducing the amount of new pre-clinical and clinical data required.

CIP-FENOFIBRATE has been approved in the U.S. and Canada under the trademarks Lipofen<sup>®</sup> and Fenomax<sup>™</sup>, respectively. CIP-TRAMADOL ER has received tentative approval from the FDA. CIP-ISOTRETINOIN's application has been filed and is pending FDA approval subject to successful completion of a safety study.

**CIP-FENOFIBRATE** is a novel patented formulation of the active ingredient fenofibrate, which is used in the treatment of hyperlipidemia, a cholesterol disorder. Hyperlipidemia is a condition characterized by high levels of low-density lipoprotein ("LDL") cholesterol and/or triglycerides (a type of fat found in the blood). Fenofibrate is known to lower LDL cholesterol and triglycerides and increase high-density lipoproteins ("HDL"), known as "good cholesterol". Fibrates have proven to be superior in lowering triglycerides and raising HDL levels. CIP-FENOFIBRATE targets a large and growing market. According to IMS, the hyperlipidemia market in the U.S. alone exceeds US\$18 billion and is made up of three primary groups of drugs: statins, fibrates and the prescription DHA/EPA market. The use of fenofibrates has escalated rapidly in recent years, with increased patient demand expected to continue. The market for existing fenofibrate formulations in the U.S. exceeded US\$2 billion during 2009, with prescriptions growing 15.2% over the previous year.

**CIP-ISOTRETINOIN** is an innovative formulation of the active ingredient isotretinoin, which is used in the treatment of severe acne. CIP-ISOTRETINOIN, which is based on the same oral Lidose<sup>®</sup> drug delivery system used with CIP-FENOFIBRATE, has been in-licensed from Galephar Pharmaceutical Research Inc. ("Galephar"). The Company's marketing rights to CIP-ISOTRETINOIN include the Americas and a majority of the Pacific Rim. In Phase I clinical studies, Cipher's innovative formulation demonstrated a significant competitive advantage in the treatment of severe, recalcitrant nodular acne. CIP-ISOTRETINOIN provides more consistent absorption under fed and fasted conditions, compared with existing isotretinoin products that exhibit a 65% reduction in absorption under fasted conditions. According to IMS, the U.S. isotretinoin market exceeded \$0.4 billion in 2009, and if converted into brand dollars, is estimated to be more than US\$1.0 billion in annual sales. Cipher was issued a product patent from the United States Patent and Trademark Office in the fourth quarter of 2008. The patent includes claims related to the reduced food effect of CIP-ISOTRETINOIN relative to currently marketed formulations.

**CIP-TRAMADOL ER** is a novel, biphasic, extended-release formulation of the active ingredient tramadol, which is used for the management of moderate to moderately severe pain. CIP-TRAMADOL ER is enabled by oral controlled-release beads, a drug delivery technology licensed from Galephar. The novel formulation means that CIP-TRAMADOL ER delivers extended-release drug delivery properties, with once-daily dosing, supporting ease-of-use for physicians

and a high level of compliance among chronic pain sufferers. Until recently, pain sufferers typically required three to five doses of tramadol per day. While Cipher is one of three companies with a once-daily dose, the Company believes there is sufficient opportunity in the pain relief market for its tramadol capsule, due to the size of the market and CIP-TRAMADOL ER's unique attributes. According to IMS, the U.S. market for extended release formulations of tramadol exceeded \$0.2 billion which only represents 4.2% of the total tramadol immediate release and extended release prescription market. The total tramadol market exceeded 27 million prescriptions in 2009 with an annual growth rate in prescriptions of 6.2%.

## **PRODUCT UPDATE:**

### **CIP-FENOFIBRATE**

CIP-FENOFIBRATE is the first product from the current pipeline to successfully receive approval from the FDA and the Therapeutic Products Directorate ("TPD") of Health Canada. The primary target market for the product is the United States.

Cipher's U.S. marketing and distribution partner is Kowa Pharmaceuticals America, Inc. ("Kowa"). Lipofen is the lead product for Kowa as it seeks to build its presence in the important primary care space.

The agreement with Kowa is for a period of ten years and they have the right to extend the term for two additional two-year periods. Under the terms of the agreement, Cipher received a US\$2 million up-front licensing payment and could receive additional milestone payments of up to US\$20 million if certain net sales targets are achieved. Cipher also receives a royalty on a percentage of net sales, which escalates from the mid-teens to mid-twenties based on annual sales achieved and the level of promotional effort by Kowa. These payments are reflected in Cipher's net revenue, which incorporates direct product-related expenses and amounts due to Galephar, Cipher's technology partner. Over the term of the agreement, after product-related expenses are deducted and including payments to Galephar, Cipher anticipates that it will retain approximately 50% of revenue.

Lipofen was launched in the U.S. market in late 2007, and monthly prescriptions have shown steady growth since that time as Kowa increases coverage of the primary care physicians in its targeted regions and expands its sales force. Kowa's sales force grew to approximately 250 at the end of the first quarter to support the launch of their pitavastatin product, LIVALO<sup>®</sup>, planned for the second quarter of 2010. A US\$1 million sales milestone payment is expected to be achieved by Q3 of this year

### **CIP-ISOTRETINOIN**

In early 2007, the Company received a second approvable letter from the FDA pertaining to its CIP-ISOTRETINOIN NDA. In the letter, the FDA indicated that Cipher's application is approvable subject to the resolution of two remaining issues. In addition to one question related to Chemistry, Manufacturing and Controls, which the Company responded to, the FDA requested that Cipher provide additional safety data. The Company appealed the position taken by the FDA in its approvable letter using the formal dispute resolution process.

Subsequently, the Company had two meetings with the FDA as part of the first stage of the formal dispute resolution process. In its response to Cipher, the representative from the FDA agreed with the original view of the FDA's Division of Dermatology and Dental Products (the "Division") that a Phase III safety study was needed to further demonstrate the safety of CIP-ISOTRETINOIN.

In August 2008, the Company achieved a major milestone with the completion of a distribution and supply agreement with Ranbaxy Pharmaceuticals Inc. ("RPI"), a wholly owned subsidiary of Ranbaxy Laboratories Limited, under which Cipher granted RPI the exclusive right to market, sell and distribute CIP-ISOTRETINOIN in the United States.

Under the terms of the agreement with RPI, Cipher received an initial upfront milestone payment of US\$1 million. The agreement includes additional pre- and post-commercialization milestone payments of up to US\$23 million, contingent upon the achievement of certain milestone targets. Once the product is successfully commercialized, Cipher will also receive a royalty percentage in the mid-teens on net sales. In addition, RPI will reimburse Cipher for the costs associated with any remaining clinical studies required to obtain FDA approval, up to a predetermined cap. Any additional development costs associated with initial FDA approval will be shared equally. Cipher is responsible for all product development activities, including management of the clinical studies required by the FDA to secure NDA approval. Cipher is also responsible for product supply and manufacturing, which would be fulfilled by its partner, Galephar Pharmaceutical Research. After product-related expenses are deducted and after the recovery of Cipher's investment in the preferred shares of Galephar, approximately 50% of all milestone and royalty payments received by Cipher under the agreement will be paid to Galephar.

In Q4 2008, an important milestone was achieved when a product patent was issued by the United States Patent and Trademark Office for CIP-Isotretinoin. The patent includes claims related to the reduced food effect of CIP-ISOTRETINOIN relative to currently marketed formulations.

In the second quarter of 2009, Cipher finalized the protocol with the FDA for the Phase III safety trial under a Special Protocol Assessment ("SPA"). The study is expected to enroll more than 800 patients and be conducted over an 18-month period at 50 sites in the U.S. and Canada. The study is a randomized double-blinded trial comparing the safety profile of CIP-ISOTRETINOIN to an FDA-approved, commercially available isotretinoin product. The study, which began early in the fourth quarter of 2009, is progressing well with enrolment having reached more than 400 patients (the mid-point of the enrolment period) at the end of Q1 2010. Reaching this enrolment milestone triggered a US\$2 million payment from Ranbaxy to Cipher, which amount was received subsequent to the end of Q1.

### **CIP-TRAMADOL ER**

During the second quarter of 2008, Cipher submitted a revised NDA to the FDA for CIP-TRAMADOL ER. After considering feedback from the FDA appeal process and the results of the additional statistical sensitivity analysis of existing data suggested by the FDA, Cipher and its advisors concluded that submitting the revised NDA provided the most expeditious path to final regulatory approval. Cipher's revised NDA includes data from additional pharmacokinetic studies conducted by the Company comparing CIP-TRAMADOL ER to Ultram<sup>®</sup> ER.

Cipher's revised NDA received tentative FDA approval in February 2009. In Q3 2009, the Company filed a Paragraph IV Certification with the FDA, which states that the relevant patent listed in the FDA's Orange Book for Ultram<sup>®</sup> ER is invalid, unenforceable, and/or will not be infringed by the manufacture or sale of Cipher's drug product. Subsequently, the Company announced that Purdue Pharma Products L.P. ("Purdue") and Napp Pharmaceutical Group Ltd. filed a complaint against Cipher in the United States District Court for the Eastern District of Virginia, for alleged infringement of two U.S. patents, specifically patent number 6,254,887 and patent number 7,074,430. Under the applicable provisions of the Hatch-Waxman Act, this patent challenge can delay final FDA approval of Cipher's NDA by 30 months, or until the patent challenge is resolved, whichever occurs first.

In early Q1 2010, the Company announced that a final summary judgment had been entered in favour of Cipher in relation to the above litigation. The judgment terminates any further stay of FDA approval of Cipher's NDA under the applicable provisions of the Hatch-Waxman Act. The final judgment holds that the patents-in-suit are invalid for obviousness based on a prior decision of the United States District Court for the District of Delaware, dated August 14, 2009, invalidating the Orange Book-listed patents for Ultram<sup>®</sup> ER in litigation filed by Purdue against Par Pharmaceutical, Inc. ("Par"). That decision in the Par litigation is currently under appeal before the United States Court of Appeals for the Federal Circuit and the Court's decision is not

expected until the latter half of 2010. If Par is successful in the appeal, Cipher believes CIP-TRAMADOL ER will no longer face any further risk of litigation from Purdue in connection with the Orange Book-listed patents that were asserted against Cipher.

The Company is moving forward to obtain FDA final approval and expects a response in Q2 2010. As part of its broader CIP-TRAMADOL ER commercialization strategy, Cipher also announced that its New Drug Submission to Health Canada was accepted for review during the first quarter. The Company expects the review to be completed by early 2011.

The Company continues to conduct ongoing discussions with potential commercial partners interested in licensing CIP-TRAMADOL ER.

## NEW PRODUCTS AND OUT-LICENSING ACTIVITIES

Cipher continues to actively pursue new early stage pipeline product candidates and advance out-licensing discussion for its current products.

### REVIEW OF OPERATING RESULTS:

#### Revenues (in thousands of dollars):

For the three month periods ended March 31,

	2010	2009	\$ change in 2010	% change in 2010
Licensing revenue	918	602	316	52

For the quarter ended March 31, 2010 the Company realized licensing revenue of \$0.9 million compared to \$0.6 million in Q1 2009.

Revenue from Lipofen in Q1 2010 totalled \$0.8 million, an increase of \$0.3 million over 2009. The increase was a result of increased royalty revenue, reflecting the continued market penetration by Lipofen as Kowa increases the sales and promotion effort behind the product.

Revenue from CIP-ISOTRETINOIN was \$0.1 million in Q1 2010, the same amount as Q1 2009, which relates to revenue recognized on the Company's share of the US\$1 million up-front milestone payment received from Ranbaxy in 2008. No revenue was recognized on the Company's share of the US\$2 million milestone in Q1 2010 as the milestone was achieved at the end of the quarter.

Licensing revenue is presented on a net basis and reflects the various elements of the agreements with distribution partners, as well as amounts due to Galephar, the Company's technology partner.

#### Research and Development Expense (in thousands of dollars):

For the three month periods ended March 31,

	2010	2009	\$ change in 2010	% change in 2010
Research and development	278	229	49	21

Research and development ("R&D") expense represents the cost of the Company's drug development activities. Reported R&D expense is shown net of the amounts reimbursed by Ranbaxy for the CIP-ISOTRETINOIN Phase III clinical study during the quarter and refundable provincial tax credits. Gross R&D expenditures during Q1 2010 were \$4.1 million, which represents an increase of \$3.8 million compared to Q1 2009, driven by the CIP-ISOTRETINOIN

clinical study. The reported R&D expenditure amount of \$0.3 million for Q1 2010 is net of \$3.8 million (\$0.1 million in Q1 2009) of reimbursed expenses from Cipher's marketing partner.

The amount of future R&D expense will depend on additional clinical development requirements for the Company's current products and on development plans for any new products in-licensed by the Company.

**Operating, General and Administrative Expense ("OG&A") (in thousands of dollars):**

For the three month periods ended March 31,

	2010	2009	\$ change in 2010	% change in 2010
Operating, general & administrative	968	989	(21)	(2)

OG&A expense in Q1 2010 was \$1.0 million, the same amount as the first quarter of 2009.

**Amortization of Intangible Assets (in thousands of dollars):**

For the three month periods ended March 31,

	2010	2009	\$ change in 2010	% change in 2010
Amortization of intangible assets	176	188	(12)	(6)

The Company began amortizing the intangible rights associated with CIP-ISOTRETINOIN in the first quarter of 2009. The Company began amortizing the intangible rights related to CIP-FENOFIBRATE in January 2006.

Intangible assets have a finite life and are amortized using the straight-line method over their estimated period of useful life. Intangible assets are reviewed for impairment when events or other changes in circumstances indicate that the carrying amount of the assets may not be recoverable.

**Interest Income (in thousands of dollars):**

For the three month periods ended March 31,

	2010	2009	\$ change in 2010	% change in 2010
Interest income	6	46	(40)	(87)

Interest is earned on the Company's cash balance. In 2009, imputed interest was recorded related to the loan receivable, however, the balance of the loan receivable was received at the end of January 2010 and as a result interest income was lower in Q1 of 2010 than in the comparable period last year.

**Provision for Income Taxes:**

The Company has approximately \$22 million of future income tax assets, for which a valuation allowance has been recorded against the entire balance. These assets consist of non-capital loss carry forwards, intangible assets and R&D expenditures which are available to reduce taxable income in future years. The Company also has approximately \$2.7 million of investment

tax credits on scientific research and experimental development expenditures which are available to be applied against federal taxes otherwise payable in future years.

### Loss per Share:

For the three month periods ended March 31,

	2010	2009	\$ change in 2010	% change in 2010
Loss (in thousands of dollars)	512	777	265	34%
Basic and diluted loss per share	0.02	0.03	0.01	34%

Loss per share is calculated using the weighted average number of shares outstanding. The loss in Q1 2010 was \$0.5 million or \$0.02 per share, compared with a loss of \$0.8 million or \$0.03 per share, in Q1 2009. The improved performance in Q1 2010 was primarily a result of increased revenue generated from the Lipofen U.S. distribution agreement.

### SUMMARY OF QUARTERLY RESULTS:

#### Quarterly Statements of Income (in thousands of dollars, except per share amounts):

For the three month period ended March 31, 2010

	Q1
Licensing revenue	918
Research & development (1)	278
Operating, general and administrative	968
Amortization of property and equipment	14
Amortization of intangible assets	176
Interest income	6
Loss	(512)
Loss per share	(0.02)

(1) Reported R&D expense for Q1 2010 is net of provincial tax credits of \$70 and reimbursements from Ranbaxy for R&D expenditures for CIP-ISOTRETINOIN of \$3,787.

For the year ended December 31, 2009

	Q1	Q2	Q3	Q4	2009 Total
Licensing revenue	602	678	1,067	832	3,179
Research & development (2)	229	225	247	255	956
Operating, general and administrative	989	1,057	1,157	1,049	4,252
Amortization of property and equipment	19	18	19	13	69
Amortization of intangible assets	188	189	188	176	741
Interest income	46	27	26	25	124
Loss	(777)	(784)	(518)	(636)	(2,715)
Loss per share	(0.03)	(0.03)	(0.02)	(0.03)	(0.11)

(2) Reported R&D expense for 2009 is net of provincial tax credits of \$53 and reimbursements from Ranbaxy for R&D expenditures for the CIP-ISOTRETINOIN Phase III trial of \$4,372.

For the year ended December 31, 2008

	Q1	Q2	Q3	Q4	2008 Total
Licensing revenue	177	277	672	417	1,543
Research & development (3)	450	1,092	(220)	(19)	1,303
Operating, general and administrative	811	967	879	908	3,565
Amortization of property and equipment	17	18	18	18	71
Amortization of intangible assets	117	116	117	116	466
Recovery of legal fees and court costs	0	0	176	0	176
Interest income	138	113	119	86	456
Net Income (loss)	(1,080)	(1,803)	173	(520)	(3,230)
Earnings (loss) per share	(0.04)	(0.08)	0.01	(0.02)	(0.13)

(3) Reported R&D expenses for 2008 are net of provincial tax credits of \$440 and reimbursements from Ranbaxy for R&D expenditures for the CIP-ISOTRETINOIN Phase III trial of \$496.

## LIQUIDITY AND CAPITAL RESOURCES:

The cash balance at March 31, 2010 was \$9.1 million compared to \$9.0 million as at December 31, 2009. The Company expects that these funds, as well as revenues generated from licensing and distribution agreements (royalties and milestone payments), will be sufficient to fund current product development and operating costs.

The accounts receivable balance was \$3.4 million at March 31, 2010 compared to \$1.0 million as at December 31, 2009. The increase is primarily due to the achievement of the Phase III trial milestone for CIP-ISOTRETINOIN, which resulted in a billing of US\$2 million at the end of March.

The balance of accounts payable and accrued liabilities was \$2.2 million at March 31, 2010, compared to \$1.6 million as at December 31, 2009. The increase is in line with the higher level of commercial activity during the quarter, as shipments of Lipofen were substantially higher in Q1 of 2010 compared to Q1 of 2009.

Deferred revenue relates to amounts received in advance of revenue recognition. The balance of \$3.5 million at March 31, 2010 includes the Company's share of the US\$2 million milestone under the Ranbaxy distribution and supply agreement for achieving 50% patient recruitment of the Phase III trial (achieved at the end of Q1 2010) and previous milestone payments received under the Ranbaxy and Kowa distribution and supply agreements, net of revenue recognized to date. The deferred revenue balance at December 31, 2009 was \$2.3 million.

The development of pharmaceutical products is a process that requires significant investment. Cipher expects to incur losses from operations for the near future. R&D expenses are expected to increase, including expenses related to additions of personnel and clinical trials. General and administrative expenses are expected to increase in the future as the Company expands its business development activity, adds infrastructure and incurs additional costs.

Future cash requirements will depend on a number of factors, including the continued progress of R&D for product candidates, the timing and outcome of clinical trials and regulatory approvals, the ability to out-license approved products to distributors, the timing of payments received or made under licensing or other collaborative agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, defending against patent infringement claims, the acquisition of licenses for new products or technologies, the status of competitive products and the success of the Company in developing and maintaining markets for its products and services.

As at March 31, 2010, there are no capital lease contractual obligations. The only significant operating lease contractual obligation is the Company's office location, which expires in 2012.

## **SHARE CAPITAL:**

The Company is authorized to issue an unlimited number of shares. At March 31, 2010, and at the date of this MD&A, the Company had 24,054,878 common shares issued and outstanding.

During the three months ended March 31, 2010, the Company issued 221,500 stock options under the employee and director stock option plan, with an exercise price of \$1.60. These options vest over a four year period and expire in 2020. Total compensation cost to be recognized under these options is estimated to be \$0.3 million, which amount will be recognized over the vesting period of the stock options.

Stock-based compensation expense during the three months ended March 31, 2010 was \$0.1 million, compared to \$0.2 million in the first quarter of 2009.

No stock options were exercised in the three months ended March 31, 2010.

## **CRITICAL ACCOUNTING ESTIMATES:**

A summary of significant accounting policies is included in Note 1 of the Notes to Financial Statements for the year ended December 31, 2009. Critical accounting estimates require management to make certain judgments and estimates, which may differ from actual results. Accounting estimates are based on historical experience and other factors that management believes to be reasonable under the time frame and circumstances. Changes in management's accounting estimates can have a material impact on the financial results of the Company. The Company's critical accounting estimates are described below.

**Intangible Assets:** Management is required to estimate the recoverability of the Company's intangible assets to assess if there has been an impairment. The accounting estimates and assumptions used to determine the recoverability of these intangible assets may differ from actual results. Changes in these estimates and assumptions can have a material impact on the intangible asset balance in the financial statements.

**Income Taxes:** Management uses estimates when determining current and future income taxes. These estimates are used to determine the recovery of tax loss carry forwards, research and development expenditures, and investment tax credits.

## **FINANCIAL INSTRUMENTS:**

**Credit Risk Exposure:** The only financial instrument that is potentially subject to credit risk is accounts receivable. The Company reviews the collectability of its accounts receivable on a regular basis.

**Fair Values of Financial Assets and Liabilities:** The fair values of accounts receivable, accounts payable and accrued liabilities included in the balance sheets approximate their carrying amounts due to the relatively short period of maturity of the instruments.

## **OFF BALANCE SHEET ARRANGEMENTS:**

Future milestone payments for drug development have not been reflected in the financial statements, as the liability is contingent upon meeting certain milestones and obtaining regulatory approvals. Contingent future milestone payments for the Company's current products are \$1.4 million.

## **INTERNATIONAL FINANCIAL REPORTING STANDARDS:**

In February 2008, the CICA announced that Canadian GAAP for publicly accountable enterprises will be replaced by International Financial Reporting Standards ("IFRS") for fiscal years beginning on or after January 1, 2011. Accordingly, the conversion from Canadian GAAP to IFRS will be

applicable to the Company's reporting for the first quarter of 2011, for which the current and comparative information will be prepared under IFRS. The Company does not expect that the transition to IFRS will have a material impact on its financial results, internal control over financial reporting, disclosure controls and procedures and business activities. As part of its IFRS implementation plan, the Company will continue to review the impact on its disclosure controls and procedures and internal control over financial reporting.

The Company has established an IFRS changeover plan. The first phase of the conversion process was the diagnostic review phase. This was completed in 2009 and the results of the review were presented to the Board of Directors. The main conclusions of the diagnostic review were as follows:

- The current accounting system is adequate for the transition to IFRS
- There is no need to maintain dual recordkeeping during 2010. The information required for the presentation of comparative financial information will be available from the current system.
- None of the Company's current contracts and employment arrangements are impacted by the upcoming changeover to IFRS

The next phase of the changeover plan is the detailed planning and implementation phase and the Company will be proceeding with these phases over the course of 2010.

#### **Status of the IFRS Changeover Plan**

The following is a summary of the status of the key activities in the Company's IFRS changeover plan as at March 31, 2010. At this time we cannot quantify the impact that the future adoption of IFRS will have on our financial statements. Additional information will be provided as we progress towards the changeover date.

<b>IFRS Impact Area</b>	<b>Key Activities</b>	<b>Current Status</b>
Accounting policies and financial statement preparation	Identify differences between Canadian GAAP and IFRS accounting policies that impact the Company  Selection of IFRS 1 accounting policy choices  Identify changes required in note disclosure	The review is ongoing and expected to be completed by Q2 2010. No significant differences have been identified to date.  IFRS 1 accounting policy choices have been made  The review is ongoing
Information technology and data systems	Identify changes required to financial systems  Determine and implement processes for capturing financial information under IFRS in 2010 for comparative information	Completed – no changes required  Completed – processes are implemented
Internal control over financial reporting ("ICFR")/Disclosure controls and procedures ("DC&P")	Determine and implement processes for capturing financial information under IFRS in 2010 for comparative information	The assessment is done as changes in accounting policies and financial statement preparation are identified

IFRS Impact Area	Key Activities	Current Status
Training and communication	Education of management and Audit Committee	Key individuals involved in the changeover process have been trained
	External communication regarding IFRS status	Included in 2009 year-end MD&A and Q1 2010 MD&A
Business activities	Identify impact of changeover on contractual arrangements and employee compensation plans	Review of contracts and compensation plans has been completed and there is no impact. New contracts entered into will accommodate IFRS changes.

## BUSINESS RISKS:

**Financial:** As at March 31, 2010, the Company had cash of \$9.1 million. The Company expects these funds will be sufficient to fund current product development and operating costs. The Company incurred a net loss of \$0.5 million for the three months ended March 31, 2010 and expects to incur losses from continuing operations for the near future.

**Product:** There has been substantial litigation in the pharmaceutical industry concerning the manufacture, use and sale of new products that are the subject of conflicting patent rights. Regardless of FDA approval, should anyone commence a lawsuit with respect to any alleged patent infringement by the Company, the uncertainties inherent in patent litigation make the outcome of such litigation difficult to predict.

The Company currently has three products, two approved and one pending regulatory approval. For each of these products, the Company has filed an IND and NDA with the FDA. One NDA has received final FDA approval, one has received tentative approval and one has received an approvable letter. Final FDA approval may not be granted in a timely manner or at all, which would have a material adverse effect on the Company's business. Approvals may be refused or delayed for a number of reasons, including challenges of notices of non-infringement by patent holders. Challenges of this type are not uncommon and may delay NDA approval by up to 30 months.

**Concentration of Revenue:** A significant proportion of the Company's revenue is derived from one customer. The loss of that source of revenue for any reason would have a significant impact on the future cash flow and the financial position of the Company.

**Dependence on Strategic Partnerships and Licensees:** The Company's success depends, in large measure, on its ability to conclude in-licensing, development, manufacturing, marketing, and distribution agreements with other pharmaceutical companies. Factors that may affect the success of the Company's collaborative efforts with pharmaceutical company partners include the following:

- The Company's partners may be pursuing alternative technologies or developing alternative products, either on their own or in collaboration with others, that may be competitive with the products on which they are collaborating with the Company, which could affect their commitment to the Company's product development efforts;
- The Company's technology partners may not be able to adequately supply its products in commercial quantities, which would adversely affect revenues;
- Reductions in marketing or sales efforts or a discontinuation of marketing or sales of the Company's products by its commercial partners may reduce future revenues, which will be based on a percentage of net sales by these partners; and
- The Company's partners may terminate their collaborations with the Company, which could make it difficult for the Company to attract new partners or adversely affect how the Company is perceived in the business and financial communities.

The development of pharmaceutical products is a process that requires large investments and can take years to complete. Projects can be abandoned along the way or regulatory authorities can refuse to approve new products. With respect to projects the Company initiates, the Company will attempt to minimize risk through the judicious selection of product candidates and by focusing on improving products that have already been marketed.

**Regulation:** The cost of complying with government regulation can be substantial. Government authorities in the United States, Canada and comparable authorities in foreign countries also regulate the research and development, manufacture, testing, and safety of pharmaceutical products, as well as the approval and commercialization of such products. The regulations applicable to the Company's existing and future products may change. There can be long delays in obtaining required clearances from regulatory authorities in any country after applications are filed. Government agencies in the United States, Canada and other countries in which the Company intends to carry on business regulate pharmaceutical products intended for human use. Regulations require extensive clinical trials and other testing and government review and final approval before the Company can market its products.

Requirements for approval vary widely from country to country outside of the United States and Canada. Whether or not approved in the United States or Canada, regulatory authorities in other countries must approve a product prior to the commencement of marketing the product in those countries. The time required to obtain any such approval may be longer or shorter than in the United States and Canada.

Any failure or delay in obtaining regulatory approvals could adversely affect the market for any products the Company develops and therefore its business, results of operations, financial condition and cash flows.

#### **DISCLOSURE CONTROLS AND PROCEDURES:**

There have been no changes in the Company's internal control over financial reporting during the most recent interim period ended March 31, 2010 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Cipher Pharmaceuticals Inc.**

**Unaudited Financial Statements**

**For the Three Months Ended March 31, 2010**

**Cipher Pharmaceuticals Inc.**  
**Unaudited Balance Sheets**  
(in thousands of dollars)

	<b>March 31,</b>	<b>As at</b>	<b>December 31,</b>
	<b>2010</b>		<b>2009</b>
<b>ASSETS</b>			
<b>Current assets</b>			
Cash	\$ 9,122	\$	9,006
Accounts receivable (note 3)	3,401		967
Prepaid expenses and other current assets	338		457
Current portion of loan receivable (note 2)	-		800
	<u>12,861</u>		<u>11,230</u>
Property and equipment, net	73		86
Intangible assets, net (note 3)	3,331		3,507
	<u>\$ 16,265</u>	<u>\$</u>	<u>14,823</u>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Accounts payable and accrued liabilities	\$ 2,166	\$	1,570
Current portion of deferred revenue	1,822		1,956
	<u>3,988</u>		<u>3,526</u>
Deferred revenue	1,702		329
	<u>5,690</u>		<u>3,855</u>
<b>SHAREHOLDERS' EQUITY</b>			
Share capital (note 4)	49,948		49,948
Contributed surplus	32,387		32,268
Deficit	(71,760)		(71,248)
	<u>10,575</u>		<u>10,968</u>
	<u>\$ 16,265</u>	<u>\$</u>	<u>14,823</u>

The accompanying notes are an integral part of these unaudited financial statements

**Cipher Pharmaceuticals Inc.**  
**Unaudited Statements of Operations and Comprehensive Loss**  
(in thousands of dollars, except per share amounts)

	For the three months ended	
	March 31, 2010	March 31, 2009
<b>Revenues</b>		
Licensing revenue	\$ 918	\$ 602
<b>Expenses</b>		
Research and development	278	229
Operating, general and administrative	968	989
Amortization of property and equipment	14	19
Amortization of intangible assets	176	188
Interest income	(6)	(46)
	1,430	1,379
<b>Loss and comprehensive loss for the period</b>	<b>\$ (512)</b>	<b>\$ (777)</b>
<b>Basic and diluted loss per share (note 5)</b>	<b>\$ (0.02)</b>	<b>\$ (0.03)</b>

The accompanying notes are an integral part of these unaudited financial statements

**Cipher Pharmaceuticals Inc.**  
**Unaudited Statements of Deficit**  
(in thousands of dollars)

	For the three months ended		For the
	March 31, 2010	March 31, 2009	year ended December 31, 2009
<b>Deficit, beginning of period</b>	<b>\$ (71,248)</b>	<b>\$ (68,533)</b>	<b>\$ (68,533)</b>
Loss for the period	(512)	(777)	(2,715)
<b>Deficit, end of period</b>	<b>\$ (71,760)</b>	<b>\$ (69,310)</b>	<b>\$ (71,248)</b>

The accompanying notes are an integral part of these unaudited financial statements

**Cipher Pharmaceuticals Inc.**  
**Unaudited Statements of Cash Flows**  
(in thousands of dollars)

**For the three months ended**  
**March 31,                      March 31,**  
**2010                                      2009**

**Cash provided by (used in)**

**Operating activities**

Loss	\$	(512)	\$	(777)
Items not affecting cash				
Amortization of property and equipment		14		19
Amortization of intangible assets		176		188
Stock-based compensation expense		119		161
Imputed interest		-		(28)
		(203)		(437)
Net change in non-cash operating items		(480)		(831)
		(683)		(1,268)

**Investing activities**

Proceeds from loan receivable		800		612
Purchase of property and equipment		(1)		-
Acquisition of intangible rights		-		(122)
		799		490

<b>Increase (Decrease) in cash</b>		116		(778)
<b>Cash, beginning of period</b>		9,006		9,881
<b>Cash, end of period</b>	\$	9,122	\$	9,103

The accompanying notes are an integral part of these unaudited financial statements

**Cipher Pharmaceuticals Inc.**  
**Notes to Unaudited Financial Statements**  
**March 31, 2010**  
**(in thousands of dollars, except per share amounts)**

## **1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### **Basis of presentation**

The accompanying unaudited interim financial statements of the Company have been prepared in accordance with accounting principles generally accepted in Canada for interim reporting. Accordingly, these financial statements do not include all of the disclosures required by generally accepted accounting principles for annual financial statements and should be read in conjunction with the annual financial statements of the Company. In the opinion of management, all adjustments considered necessary for fair presentation have been included. All such adjustments are of a normal recurring nature. Operating results for the three months ended March 31, 2010 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2010.

There have been no changes to the accounting policies as described in Note 1 to the financial statements for the year ended December 31, 2009.

## **2 LOAN RECEIVABLE**

During the quarter ended March 31, 2010, the Company received the final instalment of \$800 as part of the deferred payment agreement from the sale of Pharma Medica Research Inc. in February 2005.

## **3 INTANGIBLE ASSETS**

The Company has entered into certain agreements with Galephar Pharmaceutical Research Inc. ("Galephar") for the rights to package, test, obtain regulatory approvals and market certain products in various countries around the world. In accordance with the terms of the agreements, the Company has acquired these intangible rights through an investment in three separate series of preferred shares of Galephar. The Company may be required to pay additional amounts to Galephar in respect of the CIP-ISOTRETINOIN and CIP-TRAMADOL ER intangible rights of up to \$1,422 (US\$1,400) if certain future milestones are achieved as defined in the agreements. These additional payments will be made in the form of additional Galephar preferred share purchases. The recovery of these intangible rights is dependant upon sufficient revenues being generated from the related products currently under development and commercialization. The Company is currently amortizing the intangible rights related to CIP-FENOFIBRATE and CIP-ISOTRETINOIN.

With regard to CIP-FENOFIBRATE, in July 2007 the Company entered into a licensing and distribution agreement with Kowa Pharmaceuticals America, Inc. ("Kowa"), under which Kowa was granted the exclusive right to market, sell and distribute Lipofen in the United States. The Company received an up-front licensing payment of US\$2 million and, under the terms of the agreement, could receive additional milestone payments of up to US\$20 million based on the achievement of certain net sales targets. The Company also receives a royalty based on a percentage of net sales. These elements are reflected in licensing revenue, which also incorporates product-related expenses and amounts due to Galephar, the Company's technology partner. Revenue from licensing and distribution agreements is presented on a net basis. After product-related expenses are deducted, approximately 50% of all milestone and royalty payments received by the Company under the agreement will be paid to Galephar. Lipofen was launched in the U.S. market in 2007.

In August 2008, the Company entered into a development, distribution and supply agreement with Ranbaxy Pharmaceuticals Inc. ("Ranbaxy") under which Ranbaxy was granted the exclusive right to market, sell and distribute CIP-ISOTRETINOIN in the United States. Under the terms of the agreement, the Company received an up-front licensing payment of US\$1 million and could receive additional pre- and post-commercialization milestone payments of up to US\$23 million, based on the achievement of certain milestone targets. Once the product is commercialized, the Company will also receive a royalty based on a percentage of net sales. In addition, Ranbaxy will reimburse the Company for the costs associated with the clinical studies required by the FDA to secure NDA approval, up to a predetermined cap. Any additional development costs associated with initial FDA approval will be shared equally. The Company is responsible for all product development activities, including management of the clinical studies required by the FDA to secure NDA approval and is also responsible for product supply and manufacturing, which will be fulfilled by Galephar. During the quarter ended March 31, 2010, the Company achieved a pre-commercialization milestone as a result of reaching 50% of the patient enrolment level for the clinical trial. The milestone amount is US\$2 million and is included in accounts receivable on the balance sheet. Full payment was received subsequent to quarter end. After product-related expenses are deducted and after the recovery of Cipher's investment in the preferred shares of Galephar, approximately 50% of all milestone and royalty payments received by the Company under the agreement will be paid to Galephar.

**Cipher Pharmaceuticals Inc.**  
**Notes to Unaudited Financial Statements**  
**March 31, 2010**  
(in thousands of dollars, except per share amounts)

**4 SHARE CAPITAL**

**Authorized share capital**

The authorized share capital consists of an unlimited number of preference shares, issuable in series, and an unlimited number of voting common shares.

**Issued share capital**

There have been no changes in the Company's share capital during the period from December 31, 2008 to March 31, 2010. The following is a summary of the Company's share capital as at March 31, 2010:

	<b>Number of common shares (in thousands)</b>	<b>Amount \$</b>
Balance outstanding - March 31, 2010	24,055	49,948

**Stock option plan**

The following is a summary of the changes in the stock options outstanding from December 31, 2008 to March 31, 2010:

	<b>Number of options (in thousands)</b>	<b>Weighted average exercise price \$</b>
Balance outstanding - December 31, 2008	1,376	2.51
Granted in 2009	224	0.60
Expired in 2009	(20)	4.33
Balance outstanding - December 31, 2009	1,580	2.22
Granted during the three months ended March 31, 2010	222	1.60
Balance outstanding - March 31, 2010	1,802	2.14

At March 31, 2010, 1,034,560 options were fully vested and exercisable (721,974 at March 31, 2009).

During the three months ended March 31, 2010, the Company issued 221,500 stock options under the employee and director stock option plan, which have an exercise price of \$1.60, 25% of which vest on February 19 of each year, commencing in 2011, and expire in 2020. Total compensation cost for these stock options is estimated to be \$317. This cost will be recognized over the vesting period of the stock options.

The stock options issued during the three months ended March 31, 2010 were valued using the Black-Scholes option pricing model with the following assumptions:

Risk-free interest rate	3.50%
Expected life	10 years
Expected volatility	97%
Expected dividend	Nil

**5 LOSS PER SHARE**

Loss per share is calculated using the weighted average number of shares outstanding. The weighted average number of shares outstanding for the three months ended March 31, 2010 and March 31, 2009 was 24,054,878.

As the Company had a loss for each of the periods presented, basic and diluted loss per share are the same because the exercise of all stock options would have an anti-dilutive effect.

## Directors and Officers

### **Larry Andrews**

President and Chief Executive Officer

### **Norman Evans, C.A.**

Chief Financial Officer

### **William Garriock**

Chairman of the Board

### **Stefan Aigner, M.D., CFA.**

Director

### **William Claypool, M.D.**

Director

### **Gerald McDole**

Director

### **John Mull, M.D., F.R.C.P. (C)**

Director

### **Stephen R. Wiseman, C.A.**

Director

## Senior Management

### **Larry Andrews**

President and Chief Executive Officer

### **Norman Evans, C.A.**

Chief Financial Officer

### **Jason A. Gross, Pharm.D.**

Vice President, Scientific Affairs

### **John MacInnis**

Vice President,  
Portfolio Development and Licensing

## Shareholder Information

### **Stock Exchange Listing**

The Company's common shares are listed on the Toronto Stock Exchange under the symbol "DND".

### **Shareholder Inquiries**

Inquiries regarding change of address, transfer requirements or lost certificates should be directed to the Company's transfer agent.

### **Transfer Agent**

CIBC Mellon Trust Company  
320 Bay Street, Toronto, Ontario M5H 4A6  
inquiries@cibcmellon.com

### **Legal Counsel**

Goodmans LLP

### **Auditors**

PricewaterhouseCoopers LLP

## Investor Relations

### **Larry Andrews**

President and Chief Executive Officer  
T: 905-602-5840 ext. 324  
F: 905-602-0628  
landrews@cipherpharma.com

### **Norman Evans, C.A.**

Chief Financial Officer  
T: 905-602-5840 ext. 323  
F: 905-602-0628  
nevans@cipherpharma.com

### **Craig Armitage**

The Equicom Group Inc.  
T: 416-815-0700 ext. 278  
F: 416-815-0080  
carmitage@equicomgroup.com

Design and production by Equicom, a TMX Group company.



5650 Tomken Road, Unit 16  
Mississauga, ON L4W 4P1

T: 905-602-5840  
F: 905-602-0628

[www.cipherpharma.com](http://www.cipherpharma.com)