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NATCO PHARMA: MANUFACTURING AFFORDABLE MEDICINES

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After conducting a strategy meeting on August 31, 2015, Rajeev Nannapaneni, vice-chair and chief executive officer (CEO) of Natco Pharma Limited (NPL), was brooding over the company’s ever growing fund requirements. He believed that it was important to maintain an optimal capital structure while catering to the aspirations of the company, leading to new growth opportunities. He was evaluating the options for mobilizing financial resources through either an equity or debt route to meet the company’s capital expenditures and long-term working capital requirements of ₹3.41 billion.[[1]](#footnote-1)

BACKGROUND OF Natco Pharma Limited

Natco Pharma Limited (NPL) was incorporated on September 19, 1981, as a private limited company in India, and it began commercial operations in 1984 to manufacture life-saving drugs. On December 30, 1994, it was converted into a public limited company. NPL was founded by Rajeev’s father, Venkaiah Chowdary Nannapaneni, a technocrat turned entrepreneur, who had completed his master’s degree in pharmaceutical administration at Long Island University, New York. He had more than four decades of experience in the pharmaceutical industry; and as NPL’s chairman and managing director, he was deeply involved in the company’s new drug discovery and research programs. The company had 12 directors on its board, including two promoter directors (one of whom was Venkaiah Chowdary Nannapaneni). Rajeev joined NPL’s board in 2005 and had been looking after its day-to-day activities with the help of experienced professionals; he held two bachelor’s degrees, one in quantitative economics and the other in history, both from Tufts University, Boston.

NPL was a vertically integrated pharmaceutical manufacturing company with seven production facilities and an advanced research and development (R&D) centre that was accredited by the Government of India’s Department of Scientific and Industrial Research. The company’s manufacturing facilities were approved by various regulatory authorities, including the United States Food and Drug Administration (USFDA), the public health service of the Netherlands, the German health authority, and the pharmaceuticals and medical devices agency of Japan. The company was also certified by the World Health Organization (WHO) for its good manufacturing practices. The company was setting up a new manufacturing facility in Visakhapatnam, Andhra Pradesh, with a total investment of ₹1.2 billion, and it would commence operations in financial year (FY) 2016–17.

NPL was engaged in developing, manufacturing, and marketing active pharmaceutical ingredients (APIs) and finished dosage formulations. The company’s first product was Cardicap, an anti-anginal drug. Subsequently, the company introduced many products in the market, namely Coldact, Ferronat, Isosorbide, and Theophylline. By 1985, it had dosage forms in cardiovascular, anti-cold, anti-asthmatic, and antibiotic segments. That same year, NPL pioneered “time-release technology”[[2]](#footnote-2) in India for the dosage forms of life-saving drugs.

In the formulations segment, NPL was a leading player in the oncology domain and a preferred supplier to many multinational companies in the Indian pharmaceutical industry. NPL’s major revenue-earning brands were Veenat, Erlonat, Geftinat, Lenalid, and Sorafenat, each representing an annual turnover of more than ₹100 million. The company had just six products in the oncology segment in 2003; however, by 2015, through its constant R&D efforts, it had increased its oncology product portfolio to 26 (for the treatment of brain, breast, bone, lung, and ovarian cancers) (see Exhibit 1). The company derived 27 per cent of its revenue from the oncology division during FY 2014–15. It also had a presence in other therapeutic segments, including those relating to critical care, orthopaedics, gastrointestinal ailments, and central nervous system functioning (see Exhibit 2).

NPL had agreements with the leading international pharmaceutical companies to develop, manufacture, and supply APIs and formulations for regulated markets. NPL had also been undertaking contract research and manufacturing services and supplying to well-known companies such as Cadila Healthcare, Dr. Reddy’s Laboratories, Wyeth Pharmaceuticals, Lupin Limited, Mylan NV, and Sun Pharmaceuticals Industries Ltd. In the U.S. market, NPL had been pursuing a relatively derisked business model, wherein it manufactured generic versions[[3]](#footnote-3) of patented drugs, while its collaborating partner was typically responsible for marketing and distribution, on a profit-sharing basis. In the domestic market, NPL was selling its products through its 170-plus marketing personnel and 350 distributors spread across India. Also, the company was directly selling its products to government departments, clinics, and hospitals. The company exported goods worth ₹2.87 billion (40 per cent of its net sales) to more than 40 countries around the globe during FY 2014–15.

RESEARCH AND DEVELOPMENT

NPL had well-equipped R&D facilities in Hyderabad, which were run by qualified scientists, chemists, and pharmacists. The company had a strong research team of more than 240 people, most of them well-experienced and highly qualified personnel with expertise in biotechnology, cell biology, nano-pharmaceuticals, peptides chemistry, polymer-based chemistry, and synthetic chemistry. The company was keen on protecting its intellectual property rights to emerge as a top-class research-oriented pharmaceutical organization in India.

During FY 2014–15, NPL became the first company in India to launch hepcinat, a generic medicine, in the gastrointestinal space for the treatment of the chronic hepatitis C virus.[[4]](#footnote-4) According to estimates by the WHO, more than 150 million people had been diagnosed with hepatitis C, including 15–20 million patients in India.[[5]](#footnote-5) One noteworthy feature of NPL’s research was that it could develop life-saving drugs at an affordable cost for patients; for instance, before NPL introduced Veenat (for curing chronic myeloid leukemia), the cost for a month’s dosage was approximately ₹120,000 in the Indian market. As a result of NPL’s concerted research efforts, NPL was able to introduce Veenat at the drastically reduced price of ₹6,000. Similarly, in 2012, Natco won a compulsory licence[[6]](#footnote-6) to market Bayer’s product Nexavar (for curing kidney cancer) at a low cost of ₹8,880 for a monthly dose of 120 tablets, compared with Bayer’s price of ₹284,428.

NPL’s main focus was the oncology segment, as cancer had become a global killer disease. According to the International Agency for Research on Cancer, in 2012, 8.2 million cancer deaths occurred globally, of which 2.9 million were in developed countries and 5.3 million were in developing nations.[[7]](#footnote-7) As per data from the Indian National Cancer Registry Programme, 946,172 people were identified with cancer in 2008.[[8]](#footnote-8) As a result, extensive research on cancer therapy had been ongoing, and innovations in cancer drug research were projected to lead to global spending of US$100 billion in 2018.[[9]](#footnote-9)

The company believed that research was crucial for its growth in the long term and hence invested substantially in its R&D activities to develop niche products in various therapeutic areas; the company spent a total of ₹1.81 billion on R&D from 2010–2015 and spent 7.23 per cent of its net sales for this purpose during FY 2014–15. The company had been following an accounting policy of recording R&D expenses in its profit and loss account, as and when they were incurred. It filed 31 drug master files and 36 abbreviated new drug applications (ANDAs)[[10]](#footnote-10) with the USFDA, receiving approval with regard to 14 ANDAs; the remaining were pending approval as of August 31, 2015 (see Exhibit 3). NPL also had 179 patents to its credit in India and abroad. The company had several new products in development on account of its continuous focus on research. The growth prospects of NPL would be driven in the near future by its domestic oncology segment, hepatitis C products, and generic drugs intended for the U.S. markets.[[11]](#footnote-11)

FINANCIAL PERFORMANCE OF Natco Pharma Limited

NPL recorded net sales of ₹7.16 billion with a net profit of ₹1.53 billion on a stand-alone basis during FY 2014–15. The company’s net sales increased from ₹1.54 billion in FY 2004–05 to ₹7.16 billion in FY 2014–15, representing a compound annual growth rate (CAGR) of 16.50 per cent. The company had a tangible net worth of ₹8.79 billion and an interest cover of 7.54 times as of March 31, 2015. The company had been consistently paying dividends to its shareholders (see Exhibit 4) and outperforming its peers in the industry (see Exhibit 5). The company’s financial performance had registered impressive growth in the past 10 years (see Exhibit 6). As a result, in January 2015, the Investment Information and Credit Rating Agency of India Limited (ICRA) assigned NPL a credit rating of “A1+” for its short-term credit facilities and “AA–” for its long-term credit facilities. These ratings indicated the company’s strong operational and financial performance and its lower credit risk.

NPL’s PERFORMANCE IN THE SECURITIES MARKET

NPL’s total capital as of June 30, 2015 was ₹332.30 million, divided into 33.23 million equity shares with a face value of ₹10 each. While the promoters of NPL held a 53.76 per cent stake in its equity, domestic institutional investors held 5.64 per cent, foreign institutional/portfolio investors held 17.38 per cent, and the remaining 23.22 per cent was held by the general public. NPL’s shares were listed on both the National Stock Exchange of India Limited and the Bombay Stock Exchange Limited. The market price of NPL’s shares was quoted at ₹2,243.35 per share as of August 31, 2015, with a 52-week high/low value of ₹3,118/₹1,950 per share. The book value was ₹252.80 per share as of March 31, 2015.

PROPOSAL FOR DEBT

As NPL had been exporting its products mainly to the United States, Europe, and Latin America, it needed to invest heavily in technical know-how, plant and machinery, and buildings, both for its ongoing expansion programs and to comply with the regulatory market norms. As such, NPL had been retaining a major portion of its profits to build up its fixed assets, and the company’s working capital requirement had been increasing, owing to NPL’s enhanced operations. The company had an option to mobilize ₹3.41 billion in the form of loans from banksand financial institutions or through the issuance of debentures, as NPL’s debt–equity ratio was only 0.11 times as of March 31, 2015. Even after mobilizing funds through the debt route, the company’s debt–equity ratio would not be at a higher level. Given its sound credit rating, the company would also be able to obtain a bank loan at an indicative interest rate of 12 per cent. For tax purposes, NPL was in the 35 per cent tax bracket.

While issuing debentures, however, NPL needed to appoint a bank or financial institution as a debenture trustee to protect the interests of debenture holders and to ensure regular servicing of its debt. These debentures (with a tenure of more than 18 months) were required to be rated by an external credit-rating agency and secured by the company’s immovable assets. The interest rate on the debentures was normally linked to the credit rating, apart from market forces. Sometimes, the debentures included additional features, such as a call option (an option to redeem the debentures at a certain price before the maturity date), a put option (an option to seek redemption at a predetermined price during specific time periods), and a convertibility clause (a right to convert the debentures into equity shares of NPL based on certain terms and conditions).

The company had another option to raise funds through the collection of deposits from the public. As the public deposits were treated as unsecured loans, their indicative interest rate was 13 per cent. Manufacturing companies in India raised funds through the issuance of fixed deposits to the public/shareholders with a maximum tenure of up to three years. However, the maximum amount of capital mobilized through public deposits was restricted to 35 per cent of the company’s net worth. These instruments were regulated by the Company Law Board and were required to be rated by an external credit-rating agency. NPL could also mobilize funds through the issuance of preferred shares, for a maximum tenure of 12 years, which would carry a fixed rate of dividend.

PROPOSAL FOR QUALIFIED INSTITUTIONAL PLACEMENT

Apart from the above options, NPL could raise ₹3.41 billion through a qualified institutional placement (QIP), also referred to as a rights offering or a seasoned equity offering. Rajeev believed that NPL could invite institutional investors such as qualified institutional buyers (QIBs) instead of pursuing a rights offering or another mode of financing, primarily to reduce costs and expedite the process. The company also had an aversion to debt, mainly due to its past track record with banks and financial institutions, and it therefore preferred to use equity to meet its increased capital expenditures as a result of its R&D initiatives. Rajeev believed that the current capital market conditions were conducive to mobilizing funds through QIBs, and that the presence of these institutional investors as shareholders would enhance NPL’s image in the market. Further, NPL’s average stock price had been increasing continuously, from ₹397.16 per share during FY 2012–13 to ₹2,308.49 per share in August 2015 (see Exhibit 4). As such, in this context, he felt that the timing of an additional issue of equity in the form of a QIP would be the right move. After reviewing the legal provisions, he believed that, to mobilize the required funding, the company could issue 1.60 million equity shares (with a face value of ₹10 per share plus a premium of ₹2,120.55 per share). Essentially, he was of the view that the QIP would create value for the existing NPL shareholders in terms of its size, capacity, and growth prospects.

INDUSTRY OUTLOOK

Major pharmaceutical players worldwide had been forced to cut costs and outsource the manufacture of bulk drugs to cheaper destinations, such as India and China, due to slower growth in revenue and severe competition. Hence, Indian pharmaceutical manufacturers had an opportunity to export more and widen their reach in the U.S. and European markets for generic drugs. Indian pharmaceutical companies had approximately 60,000 generic brands covering 60 therapeutic segments.[[12]](#footnote-12)

The Indian pharmaceutical industry had a 10 per cent share of the global pharmaceutical industry in terms of volume and 2.40 per cent in terms of value (on account of generic drugs); the size of the total Indian pharmaceutical industry was US$20 billion in 2015 and expected to reach US$55 billion by 2020, with an estimated CAGR of 15.92 per cent.[[13]](#footnote-13) This growth in the industry was driven by massive export potential, increased access to health-care facilities, increased access to medical insurance, an aging population, sedentary lifestyles, unhealthy eating habits, a higher prevalence of chronic diseases due to higher stress levels, and rising per capita incomes.[[14]](#footnote-14)

Indian pharmaceutical companies primarily manufactured formulations and bulk drugs. APIs were the main components for making finished pharmaceutical products. The global API market broadly consisted of semi-regulated and regulated markets. While the regulated markets had high entry barriers in terms of compliance with norms and intellectual property rights, semi-regulated markets did not have such hurdles. Hence, products sold in regulated markets commanded a premium in pricing, in part because of their need for quality and regulatory compliance.

Throughout the world, there was an increased need for regulatory compliance and a focus on intellectual property rights in the pharmaceutical industry. Governments across the world were keen to reduce their health-care costs. As the cost of generic drugs was a fraction of the cost of patented drugs,[[15]](#footnote-15) most nations, especially developed economies, had been shifting toward these generic formulations. For example, although more than 50 per cent of worldwide prescriptions were in the form of generic drugs, in the United States, generic formulations were estimated to represent 86 per cent of all drugs in terms of volume.[[16]](#footnote-16) The U.S. government saved US$931 billion during the period 2001–2010, due to higher usage of generic drugs. Approximately 40 per cent of the generic drugs used in the United States were imported from India, and this trend was expected to increase.[[17]](#footnote-17) India exported pharmaceutical products to more than 180 countries; the United States, which represented 26.73 per cent of all exports, valued at US$4.02 billion, was the major export destination for Indian-manufactured pharmaceuticals, followed by Russia and the United Kingdom.[[18]](#footnote-18)

The export of bulk drugs, especially off-patented products (i.e., generic drugs), would drive overall exports, as such exports represented a huge opportunity from 2015–2020; the expiry of patents, coupled with innovators’ introduction of a few new molecules in the pharmaceutical market offered good opportunities for the Indian formulation and bulk drug companies.[[19]](#footnote-19) According to a Credit Analysis and Research Limited (CARE) report dated August 2014, patented drugs[[20]](#footnote-20) representing annual revenues of US$71.7 billion would go off patent in the United States between 2015 and 2017, leading to new growth opportunities for the generic drug producers.

The oncology segment also had good market potential in India, and the market was expected to achieve an annual growth rate of 20 per cent by 2020. Half of all cancer-related deaths in India were from lung cancer and oral cavity cancer (for men) and breast cancer and cervical cancer (for women). Global pharmaceutical sales increased by 6 per cent in 2014, due to the launch of new drugs for treating diseases such as hepatitis C.[[21]](#footnote-21) Further, the WHO forecasted that approximately 150 million people, or 3 per cent of the world population, were infected with the hepatitis C virus. China had the largest number of hepatitis C patients (29.7 million), followed by India (18.2 million), Egypt (11.8 million), and Indonesia (9.43 million).[[22]](#footnote-22)

CONCLUSION

After documenting a brief pharmaceutical industry outlook, Rajeev prepared a risk management policy for the company (see Exhibit 7) and mulled over the options for raising the required funds for NPL. More specifically, Rajeev tried to answer the following questions: How could NPL maintain an optimal capital structure, while meeting its growth aspirations? Would debt or equity be the better option for mobilizing financial resources to feed NPL’s growth? How should NPL position itself as a top-notch R&D-based pharmaceutical company in India?

EXHIBIT 1: Natco Pharma Limited’S ONCOLOGY PRODUCT PORTFOLIO

|  |  |  |  |
| --- | --- | --- | --- |
| **Serial Number** | **Brand** | **Therapeutic Segment** | **Dosage Form** |
| 1. | Erlonat | Lung cancer | Tablet |
| 2. | Geftinat | Lung cancer | Tablet |
| 3. | Lenalid | Multiple myeloma | Capsule |
| 4. | Sorafenat | Liver and kidney cancer | Tablet |
| 5. | Veenat | Chronic myeloid leukaemia | Capsule |
| 6. | Alphalan | Multiple myeloma | Tablet |
| 7. | Bendit | Chronic lymphocytic leukaemia | Injection |
| 8. | Clokeran | Chronic lymphocytic leukaemia | Tablet |
| 9. | Bortenat | Myeloma | Injection |
| 10. | Xpreza | Myelodysplastic syndrome | Injection |
| 11. | Desifer | Anaemia | Tablet |
| 12. | Rasburnat | Tumour lysis syndrome | Injection |
| 13. | Vorizol | Supportive cancer care | Tablet |
| 14. | Pemnat | Lung cancer | Injection |
| 15 | X-trant | Prostate cancer | Capsule |
| 16. | Zoldonat | Supportive cancer care | Injection |
| 17. | Natdox-LP | Ovarian cancer | Injection |
| 18. | Anastronat | Breast cancer | Tablet |
| 19. | Bandrone | Supportive cancer care | Tablet/injection |
| 20. | Xtane | Breast cancer | Tablet |
| 21. | Fulvenat | Breast cancer | Injection |
| 22. | Letronat | Breast cancer | Tablet |
| 23. | PT-Max | Supportive cancer care | Injection |
| 24. | Temonat | Glioma | Capsule |
| 25. | Tigi | Supportive cancer care | Injection |
| 26. | Trabec | Soft tissue sarcoma | Injection |

Note: Each Natco Pharma Limited brand from serial numbers 1–5 had an annual turnover of more than ₹100 million in fiscal year 2014–15. ₹ = INR = Indian rupee; US$1.00 = ₹66.31 on August 31, 2015.

Source: Company documents.

EXHIBIT 2: Natco Pharma Limited’S NON-ONCOLOGY PRODUCT PORTFOLIO (PHARMA SEGMENT)

|  |  |  |  |
| --- | --- | --- | --- |
| **Serial Number** | **Brand** | **Therapeutic Segment** | **Dosage Form** |
| 1. | Hepcinat | Hepatitis C\* | Tablet |
| 2. | X-Vir | Hepatitis B | Tablet |
| 3. | Glatimer | Multiple sclerosis | Injection |
| 4. | Natclovir | Anti-viral | Injection/capsule |
| 5. | T-score kit | Osteoporosis | Tablet |
| 6. | Teravir | Hepatitis B | Tablet |

Note: \*Natco Pharma Limited signed an agreement with Gilead Sciences to sell generic drugs to treat the hepatitis C virus in 101 developing countries, including India, catering to more than 100 million patients.

Source: Company documents.

EXHIBIT 3: Natco Pharma Limited’s Abbreviated New Drug Applications PENDING APPROVAL FROM the U.S. Food and Drug Administration (in US$ MILLIONs)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Brand Name** | **Molecule** | **Therapeutic Segment** | **Dosage** | **Estimated Market\*** |
| Copaxone 20 mg | Glatiramer 20 mg | Multiple sclerosis | Pre-filled syringe | 2,353.91 |
| Copaxone 40 mg | Glatiramer 40 mg | Multiple sclerosis | Pre-filled syringe | 1,516.26 |
| Entocort | Budesonide | Crohn disease | Capsules | 494.38 |
| Fosrenol | Lanthanum Carbonate | End-stage renal disease | Tablets | 114.43 |
| Gilenya | Fingolimod | Multiple sclerosis | Capsules | 1,321.66 |
| Jevtana | Cabazitaxel | Prostate cancer | Injection | 117.60 |
| Nexavar | Sorafenib | Anti-cancer | Tablets | 42.17 |
| Nuvigil | Armodafinil | Anti-depressants | Tablets | 448.60 |
| Revlimid | Lenalidomide | Multiple myeloma | Capsules | 974.16 |
| Tamiflu | Oseltamivir capsules | Influenza infection | Capsules | 519.24 |
| Tracleer | Bosentan | Hypertension | Tablets | 46.65 |
| Treanda | Bendamustine | Leukemia | Injection | 675.11 |
| Tykerb | Lapatinib Ditosylate | Anti-cancer | Tablets | 87.33 |
| Vidaza | Azacitidine | Myelodysplastic syndrome | Injection | 279.68 |

Note: \* The estimated market potential was based on sales in 2014, as per the report noted in the source below.

Source: Company documents and IMS Institute for Healthcare Informatics, *Global Outlook for Medicines through 2018*, November 2014, accessed October 2, 2018.

EXHIBIT 4: Natco Pharma Limited’s SHARE PRICE AND PAYMENT OF DIVIDENDS,  
FY 2012–13 to 2015

|  |  |  |  |
| --- | --- | --- | --- |
| **Financial Year / Month** | **Average Share Price on NSE (in ₹)** | **Rate of**  **Dividend (%)** | **Number of Natco Pharma Limited’s Shares Traded on the NSE**  **(in millions)** |
| 2012–13 | 397.16 | 40 | 16.16 |
| 2013–14 | 631.96 | 50 | 16.62 |
| 2014–15 | 1,255.68 | 50 | 22.73 |
| August 2015 | 2,308.49 | – | 2.16 |

Note: NSE = National Stock Exchange of India Limited; ₹ = INR = Indian rupee; US$1.00 = ₹66.31 on August 31, 2015.

Source: Company documents.

**EXHIBIT 5: COMPARISON OF NATCO PHARMA LIMITED AND ITS PEERS, FY 2014–15**

**(IN ₹ MILLIONS)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Financial Indicator** | **NPL** | **Alembic Pharmaceuticals**  **Limited** | **Granules India Limited** | **Ajanta Pharma Limited** | **Dr. Reddy’s Laboratories Limited** |
| Net Sales | 7,156 | 19,809 | 12,133 | 13,286 | 99,275 |
| Earnings before Interest, Tax Depreciation, and Amortization (EBITDA) | 2,270 | 4,084 | 2,127 | 4,993 | 26,139 |
| Profit After Tax (PAT) | 1,529 | 2,866 | 952 | 3,064 | 16,794 |
| EBITDA (%) | 31.72 | 20.62 | 17.53 | 37.58 | 26.32 |
| PAT (%) | 21.37 | 14.47 | 7.84 | 23.06 | 16.92 |
| R&D Expenses as % of Net Sales | 7.23 | 6.78 | 1.21 | 5.16 | 11.77 |
| Tangible Net Worth | 8,790 | 8,336 | 4,254 | 7,863 | 106,340 |
| Current Ratio (Times) | 1.11 | 1.39 | 1.25 | 2.34 | 2.22 |
| Debt–Equity Ratio (Times) | 0.11 | 0.04 | 0.58 | 0.04 | 0.09 |
| Interest Coverage Ratio (Times) | 7.54 | 367.93 | 6.88 | 99.86 | 40.97 |
| Price–Earnings Ratio (Times) | 45.38 | 13.86 | 22.28 | 32.03 | 25.90 |
| Earnings per Share (Times) | 46.17 | 15.20 | 4.67 | 34.84 | 98.60 |
| Price-to-Book Value Ratio (Times) | 8.87 | 10.25 | 4.08 | 13.78 | 5.59 |
| Market Capitalization | 80,460 | 99,716 | 26,937 | 132,763 | 500,316 |
| Enterprise Value | 72,704 | 87,087 | 20,425 | 107,775 | 616,496 |

NPL’s product portfolio consisted of complex, niche, and difficult-to-manufacture products associated with high disease incidence and sustained revenue potential. The company’s drugs (especially those used to treat cancer) were not over-the-counter drugs but were available only by prescription from specific hospitals/pharmacies. The company was also making its own active pharmaceutical ingredients through backward integration; while it was manufacturing generic versions of patented drugs, its collaborating partner was typically responsible for potential litigation costs, marketing, and distribution. NPL’s profitability was better than its peers, except Ajanta Pharma Ltd., signifying the company’s high-value and low-volume business model. The company’s main focus was on research and development (R&D), which was evident from its higher allocation of R&D funds, compared with its peers, except for Dr. Reddy’s Laboratories Ltd.

Note: NPL = Natco Pharma Limited; ₹ = INR = Indian rupee; US$1.00 = ₹66.31 on August 31, 2015; R&D = research and development; Peer comparison was done as per the suggestion made by NPL’s management; the above four peer companies in the Indian pharmaceutical industry were selected based on each company’s size, nature of operations, product profile, and focus on R&D.

Source: Company’s documents and annual reports of Alembic Pharmaceuticals Ltd., Granules India Ltd., Ajanta Pharma Ltd., and Dr. Reddy’s Laboratories Ltd. for the financial year 2014–15.

EXHIBIT 6: NatCO pharma Limited’s FINANCIAL POSITION, selected years 2004–05 to 2014–15 (in ₹ MILLION)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary of Profit & Loss Account** | **FY 2004–05** | **FY 2007–08** | **FY 2010–11** | **FY 2013–14** | **FY 2014–15** |
| Net Sales | 1,544 | 3,378 | 3,483 | 6,223 | 7,156 |
| EBITDA | 190 | 717 | 925 | 2,023 | 2,270 |
| Depreciation | 58 | 86 | 143 | 268 | 425 |
| Finance & Interest Costs | 125 | 85 | 142 | 341 | 301 |
| R&D Expenses | 0 | 0 | 193 | 407 | 517 |
| PAT | 16 | 400 | 521 | 1,102 | 1,529 |
| Dividends | 0 | 0 | 65 | 193 | 199 |
| **Summary of Balance Sheet** | **FY 2004–05** | **FY 2007–08** | **FY 2010–11** | **FY 2013–14** | **FY 2014–15** |
| Equity Share Capital | 262 | 280 | 281 | 331 | 332 |
| Reserves & Surplus | 875 | 2,116 | 3,188 | 6,998 | 8,458 |
| Long-Term Borrowings | 1,112 | 431 | 1,254 | 950 | 963 |
| Non-Current Liabilities | 157 | 19 | 350 | 537 | 212 |
| Current Liabilities | 0 | 1,198 | 1,888 | 2,947 | 3,983 |
| Total Liabilities | 2,406 | 4,044 | 6,961 | 11,763 | 13,948 |
| Net Fixed Assets | 1,051 | 1,983 | 3,301 | 6,220 | 6,735 |
| Long Term Investments | 147 | 670 | 691 | 886 | 1,311 |
| Non-Current Assets | 61 | 6 | 634 | 1,284 | 1,460 |
| Current Assets | 1,147 | 1,385 | 2,335 | 3,373 | 4,442 |
| Total Assets | 2,406 | 4,044 | 6,961 | 11,763 | 13,948 |

Note: ₹ = INR = Indian rupee; US$1.00 = ₹66.31 on August 31, 2015; FY = financial year; EBITDA = earnings before interest, taxes, depreciation, and amortization; R&D = research and development; PAT = profit after tax.

Source: Company documents.

EXHIBIT 7: Natco pharma limited’s RISK MANAGEMENT policy

|  |  |
| --- | --- |
| **Nature of Risk** | **Management of Risk** |
| **1**. NPL had a relatively high concentration risk because of its dependence on certain key molecules and its limited presence in the regulated markets. For instance, the company derived 27 per cent of its income in FY 2014–15 from a single therapeutic segment—oncology. Further, persistence of higher margins might remain a challenge in future. | NPL, a market leader in the oncology segment, had been making constant efforts to diversify and introduce new products in new therapeutic areas. In the past, in an effort to strengthen its product portfolio, NPL had launched pharmaceutical products related to swine flu, osteoporosis, gastrointestinal problems, and ailments of the central nervous system. NPL had also upgraded its R&D facilities in Hyderabad operated by qualified and experienced scientists/pharmacists. The company had spent ₹1.81 billion towards R&D from 2010 to 2015. It filed 31 drug master files and 36 ANDAs with the USFDA, and had received approval with regard to 14 ANDAs as of August 31, 2015. NPL had 179 patents to its credit. Hence, the risk was considered to be low. |
| **2**. NPL’s major revenue was derived from generic drugs; revenue from the sales of generic drugs would decline gradually, due to the launch of new versions of drugs by other firms in the market. So the company’s growth in future might be driven by its ability to introduce and successfully commercialize new, complex, and niche APIs and formulations. | The company had six products in the oncology segment in 2003, and its constant R&D efforts increased its portfolio to 26 products by 2015. It also had a major presence in other therapeutic segments, including for treatments related to critical care, orthopaedics, gastrointestinal ailments, and central nervous system functioning (see Exhibits 1 and 2). The company could unleash its market potential in the years to come, after approval of the ANDAs filed with the USFDA (see Exhibit 3). As NPL was a vertically integrated pharmaceutical company with focus on R&D, this risk could be addressed. |
| **3**. NPL had ambitious plans for growth in terms of expansions; however, it might face market risk, making it difficult for NPL to sell its products in the future. | NPL was selling its products through its 170-plus marketing personnel and 350 distributors spread across India. Also, the company was directly selling its products to government departments, clinics, and hospitals. It developed good rapport with medical professionals and disseminated knowledge about its products by organizing various campaigns and drug donation programs. The company was exporting to more than 40 countries, covering all five continents around the globe. As its production facilities were certified by regulatory authorities, the marketing of its products might not be an issue. |
| **4**. India’s drug formulations industry was vulnerable to changes in government policies, including price controls such as the drug pricing control order (DPCO), 2013.\* For instance, the 348 essential drugs, as per the National List of Essential Medicines 2011, should be available at a reasonable cost. As NPL’s products were covered under that list, its operations could be adversely affected by a change in policy. | As this risk was considered to be non-diversifiable, NPL had been concentrating on manufacturing drugs that had the fewest controls. |
| **5**. The company was operating in a highly regulated industry, where it might face regulatory and litigation risks. For instance, the company’s manufacturing facilities needed to continuously comply with the regulatory norms of the USFDA. It also needed to manage environmental risks because it engaged in the production of chemicals. | NPL had been pursuing a relatively derisked business model, wherein it manufactured generic versions of patented drugs, while its collaborating partner managed the potential litigation costs and the marketing and distribution on a profit-sharing basis. The company had also obtained suitable and adequate product liability insurance. The company’s API plant was a zero-discharge facility, and it had a system of recycling the various solvents to ensure improved productivity and yields. The company’s manufacturing facilities complied with the USFDA, the public health service of the Netherlands, the German health authority, and Japan’s pharmaceuticals and medical devices agency. NPL also had waste management and environment protection systems to comply with various laws. Hence, these risks might have minimal impact on the company. |

EXHIBIT 7 (CONTINUED)

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| **Nature of Risk** | **Management of Risk** |
| **6**. In the past, NPL had diversified its operations into non-pharmaceutical fields (e.g., Krishnapatnam Port Company Limited)\*\* and incurred losses that ultimately had an adverse impact on its credit record with banks and other financial institutions. As such, the risk of a diversion of funds might not be ruled out in future. | The company had learned from its past mistakes and was committed to focus only on its core area—the pharmaceutical industry. The risk was misplaced, as the present proposal was meant for the mobilization of funds for its R&D-based capital expenditures and long-term working capital requirements. |
| **7**. As considerable time (three or more years) and a substantial amount of money would be required for the testing, reviewing, developing, and marketing of generic drugs, the company might not find the market for its products as projected, thereby making it unable to achieve an adequate return on its invested capital. Further, investors would expect more predictable profitability and less volatility in NPL’s earnings. | To address this risk, NPL was launching many products in the market. As it was earning good profit margins and also had five oncology products with annual turnover of more than ₹100 million, it would be able to meet the huge costs for the commercialization of its products. The company could reduce volatility in its earnings once it consolidated its research efforts in terms of new drug discovery. |
| **8**. The company was exporting its products to more than 40 countries and also importing a portion of its raw materials and capital equipment. It might face exchange-rate risks in its export/import transactions. | NPL had earnings in foreign currency to the extent of ₹3.16 billion and against expenses in foreign currency to the tune of ₹0.96 billion during FY 2014–15; as such, it had a natural hedge of up to 30.37 per cent. The company borrowed money in foreign currency to expand its coverage in terms of a natural hedge. The company had not recorded any major losses due to volatility in foreign exchange rates in the past (NPL’s exports were higher than its imports and the ₹ depreciated against the US$, in general). Hence, its exchange-rate risk was nominal. |

Note: NPL = Natco Pharma Limited; FY = financial year; R&D = research and development; ₹ = INR = Indian rupee; US$1.00 = ₹66.31 on August 31, 2015; ANDAs = abbreviated new drug applications; USFDA = United States Food and Drug Administration; APIs = active pharmaceutical ingredients; \*The Drug Pricing Control Order (DPCO), 2013, enabled the Indian government to regulate the prices of 348 essential drugs, thereby making them available to the public at an affordable cost; \*\*Krishnapatnam was a port town located in Nellore district of Andhra Pradesh state. According to history, Sri Krishnadevaraya, a king in South India, operated this port; as such it is named after him; NPL incorporated the Krishnapatnam Port Company Limited on March 15, 1996 by entering into a memorandum of understanding with the Government of Andhra Pradesh to this effect.

Source: Company documents; Krishnapatnam Port Company Limited, “Schedule – I Disclosure as per SEBI Guidelines for the Issue of Debentures on Private Placement Basis,” Bombay Stock Exchange, accessed October 2, 2018, www.bseindia.com/downloads/ipo/200933116251KPCL-Disclosure%20Document%20-Final.pdf; “About Port, Krishnapatnam Port, accessed October 2, 2018, www.krishnapatnamport.com/about\_port.html; Nalinakanthi V., “All You Wanted to Know about: DPCO,” *Hindu Business Line*, September 29, 2014, accessed July 1, 2016, www.thehindubusinessline.com/opinion/all-you-wanted-to-know-about-dpco/article6458442.ece.

1. Swaraj Singh Dhanjal, “Natco Pharma Raises ₹350 Crore through QIP,” Live Mint, September 11, 2015, accessed December 19, 2015, www.livemint.com/Companies/5TKROQFj6IUSqTvpzIFJIK/Natco-Pharma-raises-Rs350-crore-through-QIP.html. NPL wanted to invest ₹2.50 billion in technical know-how, plant and machinery, and buildings for its ongoing expansion programs and also to comply with the regulatory norms; long-term working capital was the net working capital NPL built up in an attempt to improve its liquidity position (i.e., its current ratio stood at 1.11 times as of March 31, 2015, and the company wanted to increase it to 1.33 times, in accordance with the prevailing practice in the Indian corporate/banking sector); ₹ = INR = Indian rupee; all currency amounts are in ₹ unless otherwise specified; US$1.00 = ₹66.31 as of August 31, 2015; [↑](#footnote-ref-1)
2. Time-release technology dissolved a medicine gradually in the patient’s bloodstream, thereby reducing the frequency of doses on a given day. [↑](#footnote-ref-2)
3. After the patent for a brand-name drug expired, generic versions of the drug could be introduced to the market. Generic drugs were bio-equivalent to patented drugs in terms of form, dosage, effect, strength, intended use, and side effects; IMS Institute for Healthcare Infomatics, *Global Outlook for Medicines through 2018*, November, 2014, accessed June 18, 2016. [↑](#footnote-ref-3)
4. Natco Pharma Limited, *Annual Report 2014–15, 28,* accessed December 10, 2016, www.natcopharma.co.in/investors/annu

   al-reports/. Hepatitis C was a viral disorder caused by the transfusion of unsafe blood, contamination from tattoo needles, or as a result of surgery. [↑](#footnote-ref-4)
5. CARE, “*Report on Pharmaceutical Industry*”, CARE Limited, May 14, 2014, accessed May 4, 2016. [↑](#footnote-ref-5)
6. A compulsory licence allowed a generic drug maker, on payment of a royalty to the patent holder, to produce and market a patented drug at a reasonable price, even if the patent was still in force. The licence was allowed to make the drug affordable to the general public. [↑](#footnote-ref-6)
7. Natco Pharma Limited, op. cit., 7. [↑](#footnote-ref-7)
8. Ibid., 8. [↑](#footnote-ref-8)
9. Ibid., 22. [↑](#footnote-ref-9)
10. US Department of Health and Human Services, “Drug Master Files: Guidelines,” US Food and Drug Administration, accessed May 4, 2016, www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm122886.htm; US Department of Health and Human Services, “Abbreviated New Drug Application (ANDA): Generics,” U.S. Food and Drug Administration, accessed May 4 2016, www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics. A drug master file (DMF) consisted of detailed confidential information related to manufacturing facilities, processes, packaging, and storing of a specific life-saving drug. Drug manufacturers filed DMFs with the USFDA with a view to receiving approval for abbreviated new drug applications. An abbreviated new drug application (ANDA) contained data related to the manufacturing of a generic product; after receiving approval from the USFDA, the drug could be manufactured and marketed by the applicant in the U.S. markets. Generic drugs were referred to as abbreviated new drug applications because these applications did not include data related to pre-clinical (i.e., animal) and clinical (i.e., human) data to prove the safety and effectiveness of the drugs. [↑](#footnote-ref-10)
11. Nalinakanthi V., “Natco Pharma: Healthy Prospects,” *Hindu Business Line*, June 5, 2016, accessed June 18, 2016, www.thehindubusinessline.com/portfolio/firm-calls/natco-pharma-healthy-prospects/article8693684.ece. [↑](#footnote-ref-11)
12. CARE, op. cit. [↑](#footnote-ref-12)
13. India Brand Equity Foundation, “Indian Pharmaceuticals Industry Analysis,” IBEF, January 16, 2016, accessed July 6, 2016, www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentation. [↑](#footnote-ref-13)
14. CRISIL, “Acute Ailments Prominent in India, but Chronic Drugs Drive Formulation Sales,” CRISIL Limited, May 15, 2015, accessed May 5, 2016.” [↑](#footnote-ref-14)
15. After funding extensive R&D and clinical trials, a pharmaceutical company required billions of dollars and 10–12 years to develop and market an innovative drug. CARE, op. cit. [↑](#footnote-ref-15)
16. Natco Pharma Limited, op. cit., 23. [↑](#footnote-ref-16)
17. Ibid. [↑](#footnote-ref-17)
18. CARE, op. cit. [↑](#footnote-ref-18)
19. CRISIL, “Indian Pharmaceutical Manufacturers’ Growth to Remain Healthy,” March 18, 2016, accessed May 5, 2016, www.crisilresearch.com/industryasync.jspx?serviceId=30&State=null#storyId#118624#sectionId#1330#newsFeedId#undefined. [↑](#footnote-ref-19)
20. Patented drugs were non-prescription medicinal preparations protected by a trademark and whose proprietary contents were not completely disclosed. [↑](#footnote-ref-20)
21. CRISIL, “New Products Drive Up Global Pharma Sales,” CRISIL Limited, May 15, 2015, accessed May 5 2016. [↑](#footnote-ref-21)
22. CARE, op. cit. [↑](#footnote-ref-22)